US009403025B2

(12) **United States Patent**
Mashiach et al.

(10) **Patent No.: US 9,403,025 B2**
(45) **Date of Patent: Aug. 2, 2016**

(54) **ELECTRICAL CONTACTS ON A MEDICAL DEVICE PATCH**

(71) Applicants: **Adi Mashiach**, Tel Aviv (IL); **Tim Ruytjens**, Mortsel (BE)

(72) Inventors: **Adi Mashiach**, Tel Aviv (IL); **Tim Ruytjens**, Mortsel (BE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/600,352**

(22) Filed: **Jan. 20, 2015**

(65) **Prior Publication Data**

US 2016/0001084 A1 Jan. 7, 2016

Related U.S. Application Data

(63) Continuation of application No. 13/952,027, filed on Jul. 26, 2013, now Pat. No. 8,948,871.

(60) Provisional application No. 61/676,327, filed on Jul. 26, 2012.

(51) **Int. Cl.**
A61N 1/00 (2006.01)
A61N 1/378 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61N 1/3787*** (2013.01); ***A61B 17/0482*** (2013.01); ***A61N 1/0526*** (2013.01); ***A61N 1/0548*** (2013.01); ***A61N 1/0558*** (2013.01); ***A61N 1/3601*** (2013.01); ***A61N 1/36003*** (2013.01); ***A61N 1/3605*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/0482; A61N 1/0526; A61N 1/0548; A61N 1/0558; A61N 1/36003; A61N 1/3601; A61N 1/3605; A61N 1/3606; A61N 1/36071; A61N 1/36075; A61N 1/3611; A61N 1/36117; A61N 1/36125; A61N 1/36132; A61N 1/36189; A61N 1/37229; A61N 1/375; A61N 1/3787; H02J 7/025; H04B 5/0031; H04B 5/0037; H04B 5/0081; H04B 5/0093; Y10T 29/49018
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,415,170 B1 7/2002 Loutis et al.
6,587,728 B2 7/2003 Fang et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0 838 232 B1 5/2002
WO WO2011/092449 A1 4/2011
(Continued)

OTHER PUBLICATIONS

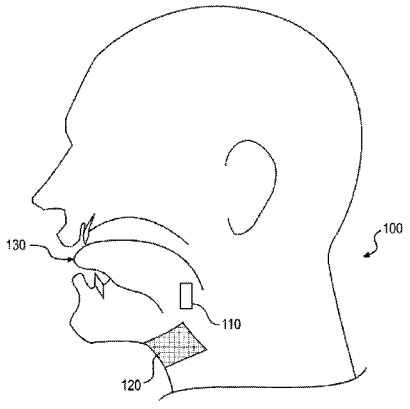
PCT International Search Report and Written Opinion for International Application No. PCT/IB13/02104, dated Feb. 10, 2014 (10 pgs.).

Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Finnegan, Henderson, Farabow, Garret & Dunner, LLP

(57) **ABSTRACT**

A device for conveying power from a location external to a subject to a location within the subject may include a flexible carrier and an adhesive on a first side of the carrier. A coil of electrically conductive material may be associated with the flexible carrier. A mechanical connector may be associated with the carrier opposite the adhesive, wherein the mechanical connector is configured to retain a housing and permit the housing to rotate relative to the flexible carrier. At least one electrical portion may be associated with the carrier in a manner permitting electrical connection to be maintained between the flexible carrier and the housing as the housing is rotated.

15 Claims, 14 Drawing Sheets



(51) **Int. Cl.**

A61N 1/05	(2006.01)
A61B 17/04	(2006.01)
A61N 1/36	(2006.01)
A61N 1/372	(2006.01)
H04B 5/00	(2006.01)
H02J 7/02	(2016.01)
A61N 1/375	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N1/3606*** (2013.01); ***A61N 1/3611*** (2013.01); ***A61N 1/36071*** (2013.01); ***A61N 1/36075*** (2013.01); ***A61N 1/36117*** (2013.01); ***A61N 1/36125*** (2013.01); ***A61N 1/36132*** (2013.01); ***A61N 1/36189*** (2013.01); ***A61N 1/375*** (2013.01); ***A61N 1/37229*** (2013.01); ***H02J 7/025*** (2013.01); ***H04B 5/0037*** (2013.01); *H04B 5/0031* (2013.01); *H04B 5/0081* (2013.01); *H04B 5/0093* (2013.01); *Y10T 29/49018* (2015.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,024,248	B2	4/2006	Penner et al.	
7,141,034	B2	11/2006	Eppstein et al.	
7,214,107	B2	5/2007	Powell et al.	
7,231,256	B2	6/2007	Wahlstrand et al.	
7,444,184	B2 *	10/2008	Boveja et al.	607/40
7,720,549	B2	5/2010	Schroeppel et al.	
7,896,809	B2	3/2011	Simpson et al.	
7,979,940	B1	7/2011	Wilkins	
8,214,031	B1	7/2012	Sexton	
8,295,936	B2	10/2012	Wahlstrand et al.	
8,301,243	B2	10/2012	Stevenson et al.	
8,343,086	B2	1/2013	Dacey, Jr. et al.	
2008/0275327	A1	11/2008	Faarbaek et al.	
2009/0240303	A1	9/2009	Wahlstrand et al.	
2009/0306728	A1	12/2009	Wright et al.	
2011/0071591	A1	3/2011	Bolea et al.	
2012/0108922	A1	5/2012	Schell et al.	
2012/0109261	A1	5/2012	Stancer et al.	
2012/0116314	A1	5/2012	Sexton	
2012/0197098	A1	8/2012	Donnay et al.	
2012/0259239	A1	10/2012	Chenaux et al.	

FOREIGN PATENT DOCUMENTS

WO	WO2011/039329	A1	7/2011
WO	WO2012/158748	A1	11/2012

* cited by examiner

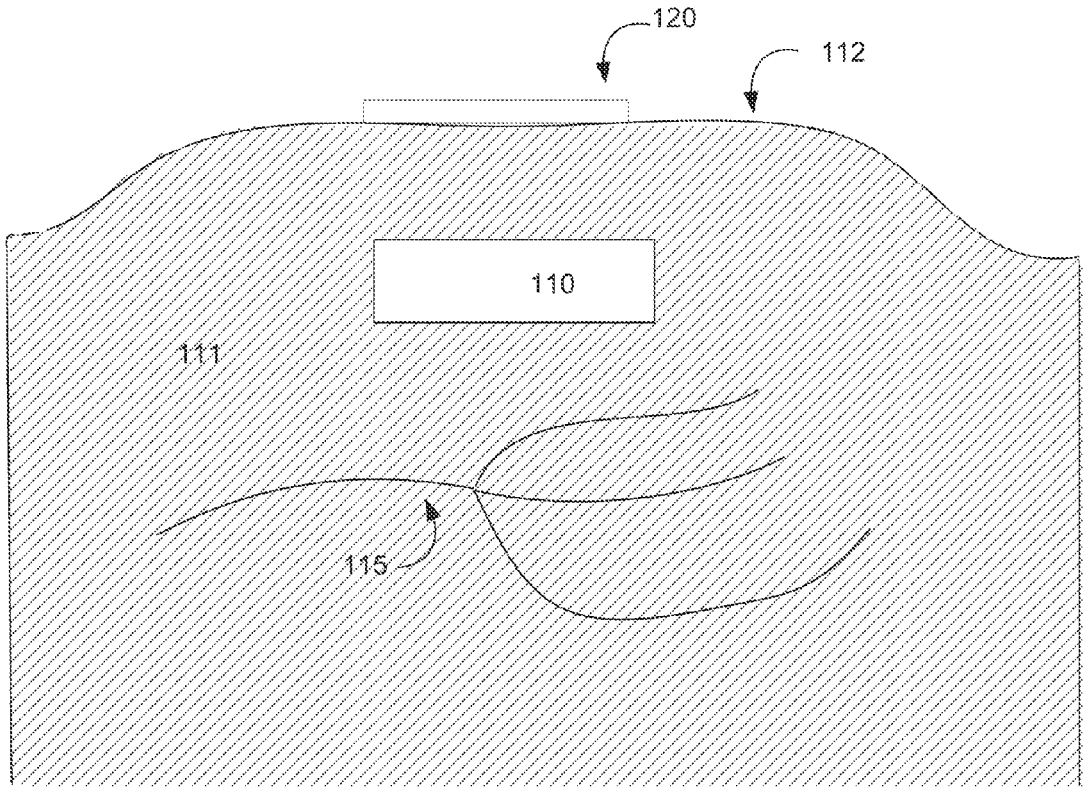


FIG. 1

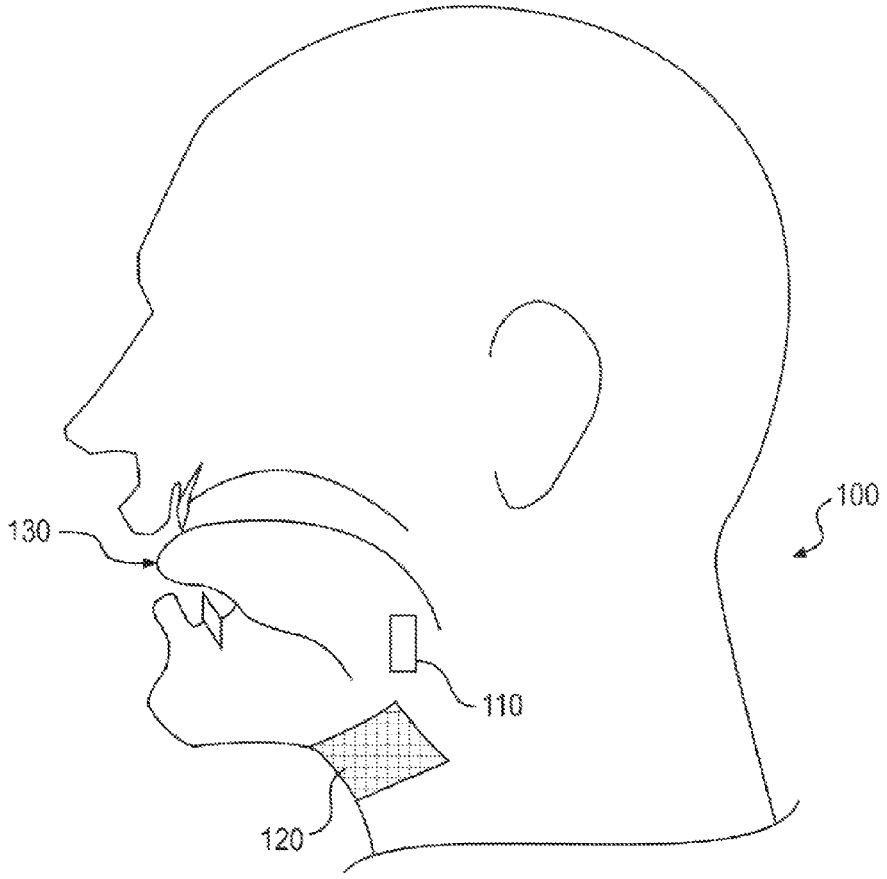


Fig. 2

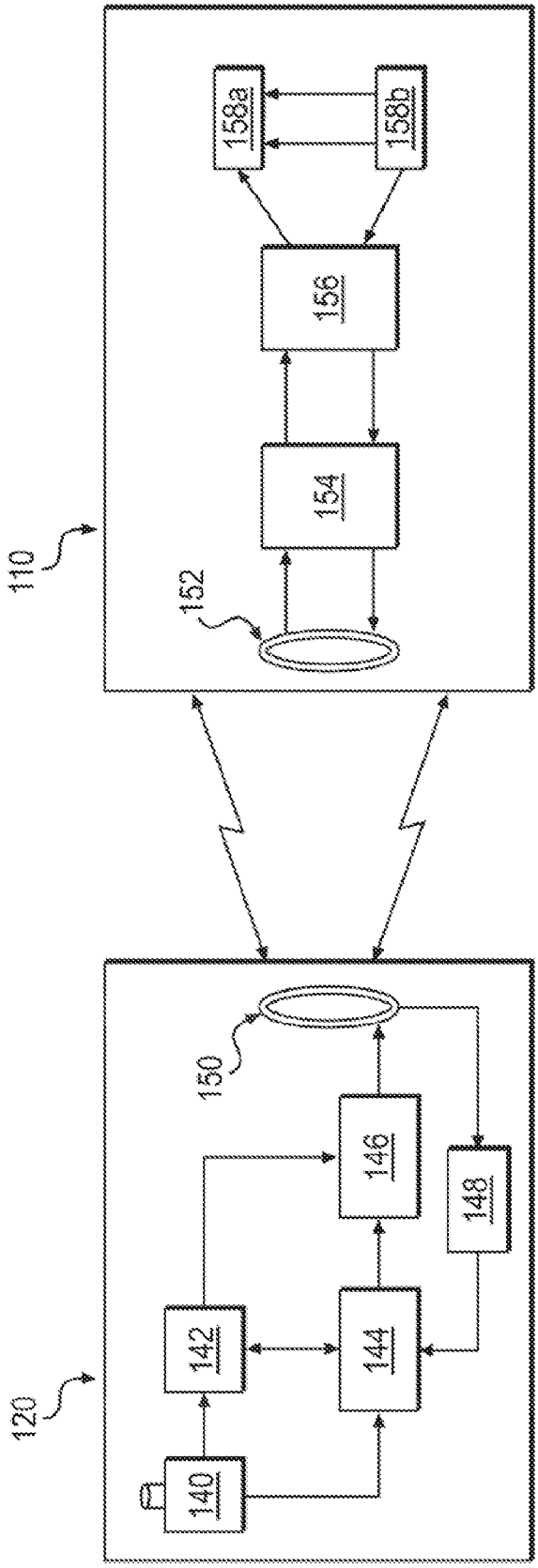


Fig. 3

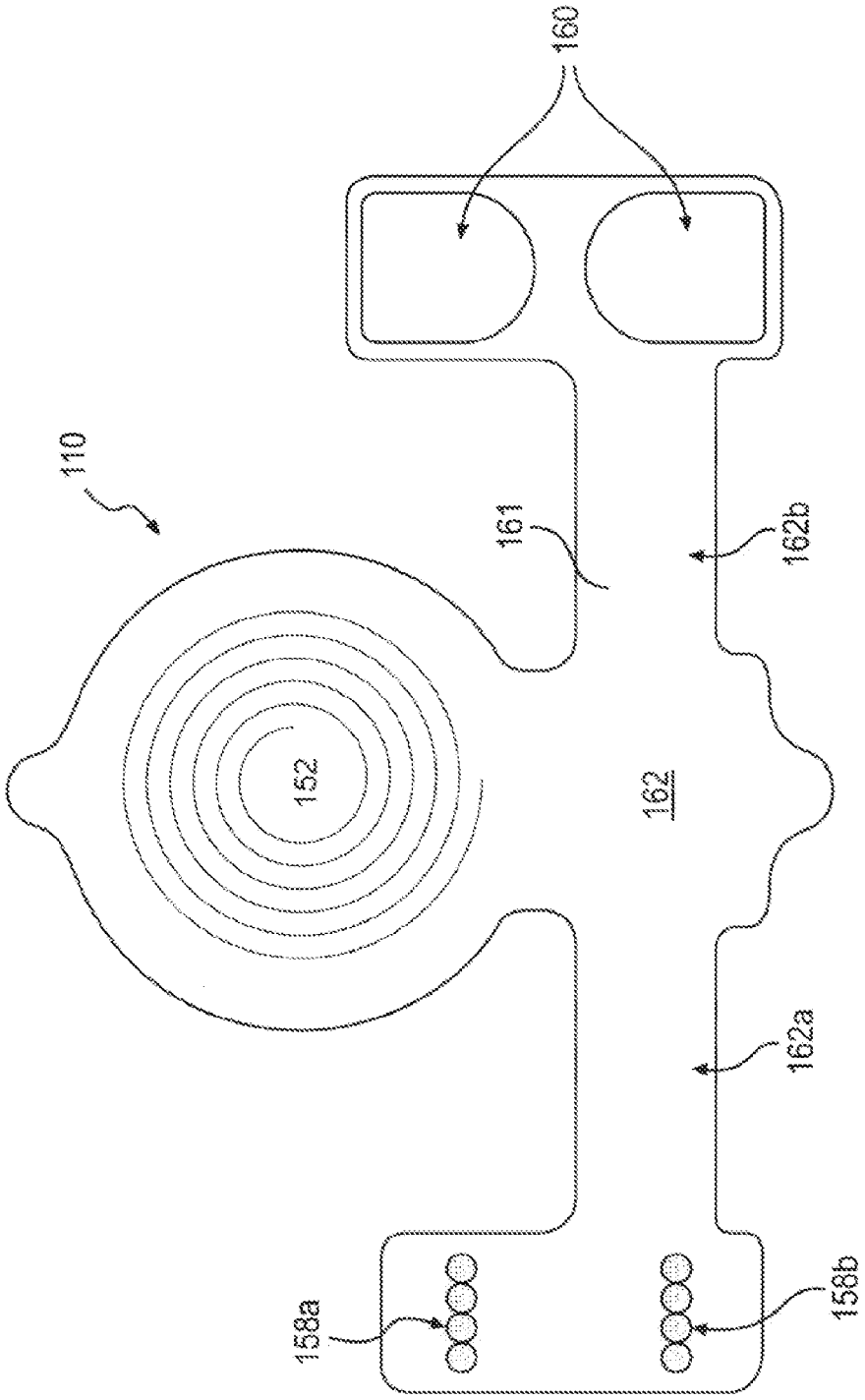


Fig. 4

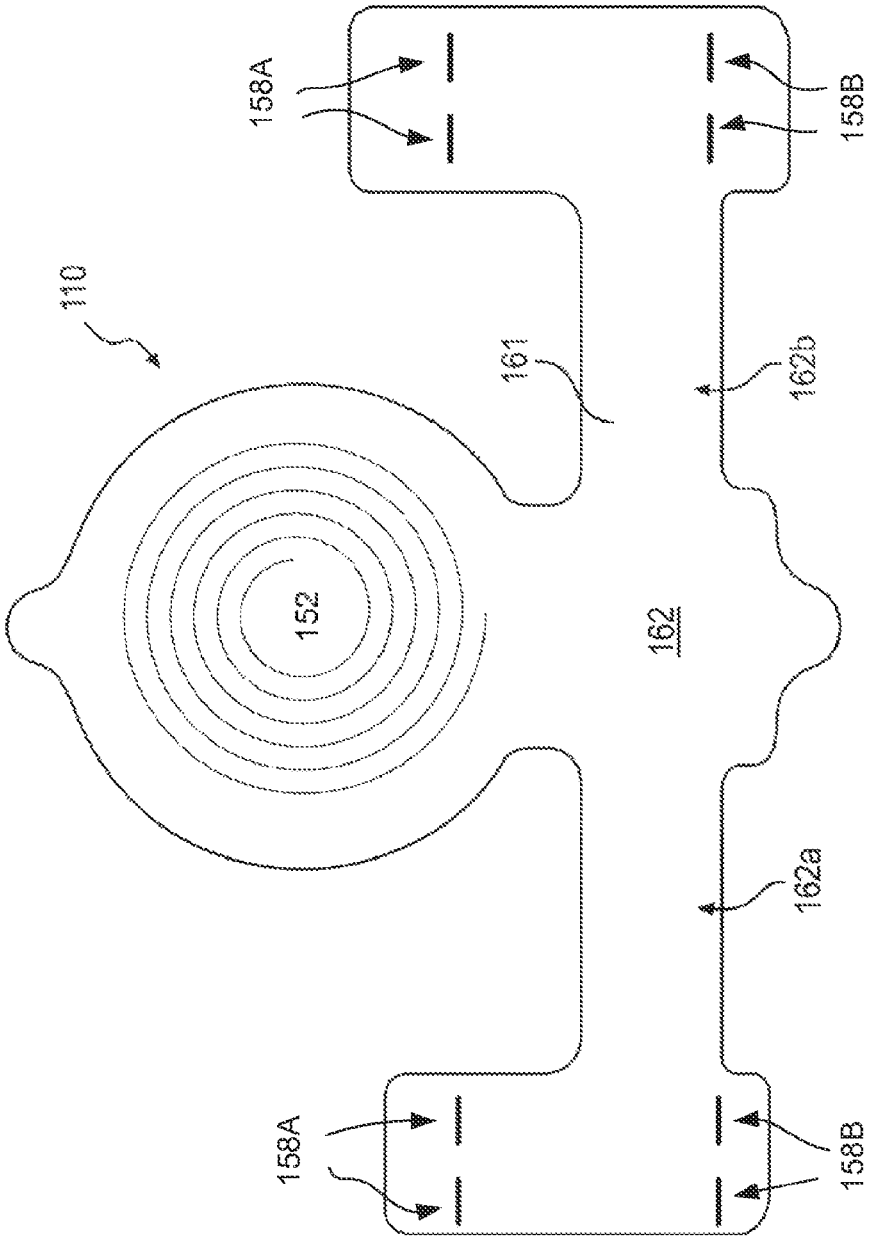


Fig. 5

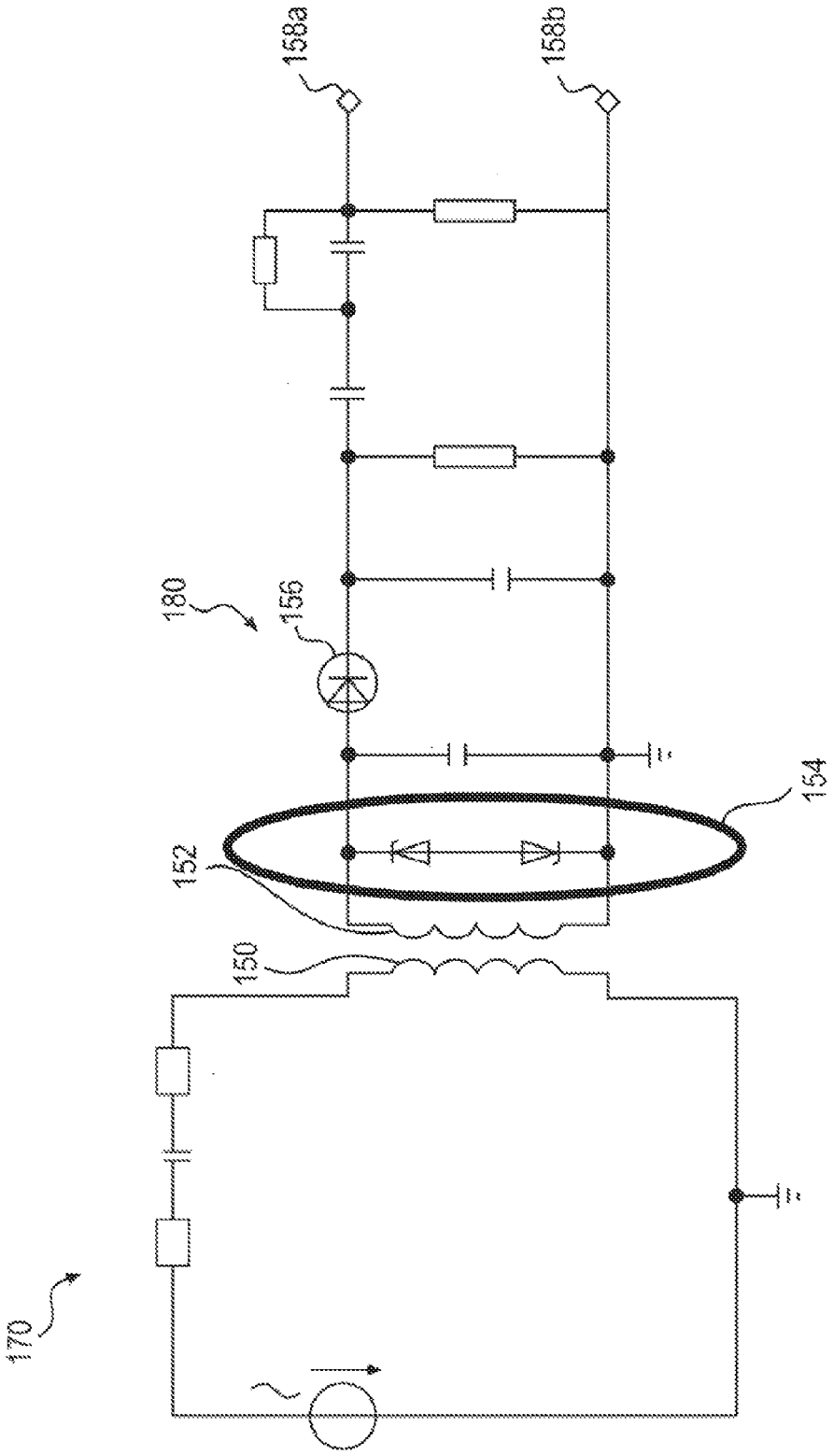


Fig. 6

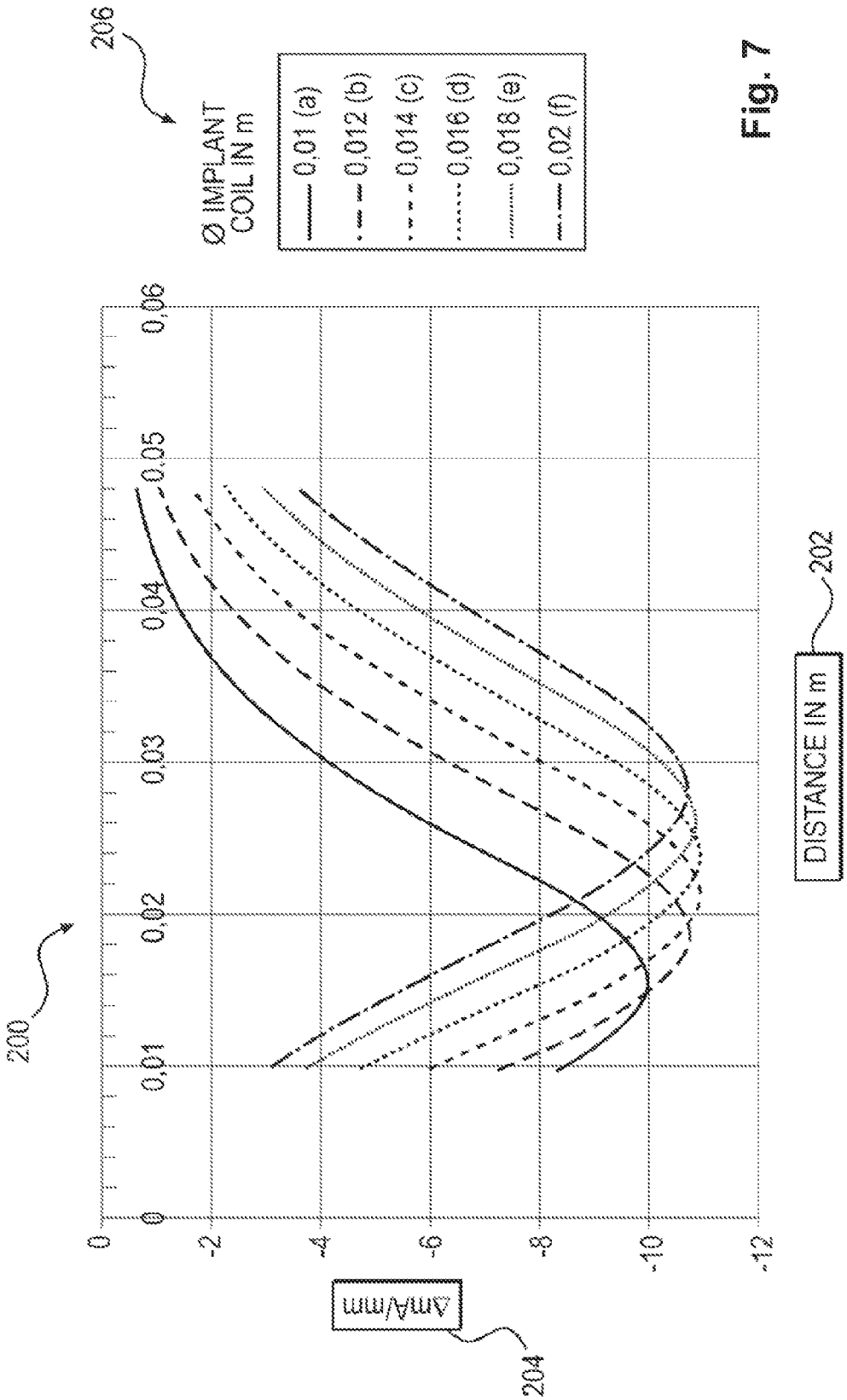

206
Ø IMPLANT COIL IN m
0,01 (a)
0,012 (b)
0,014 (c)
0,016 (d)
0,018 (e)
0,02 (f)
200
0
0,01
0,02
0,03
0,04
0,05
0,06
DISTANCE IN m
202
0
-2
-4
-6
-8
-10
-12
ΔmA/mm
204

Fig. 7

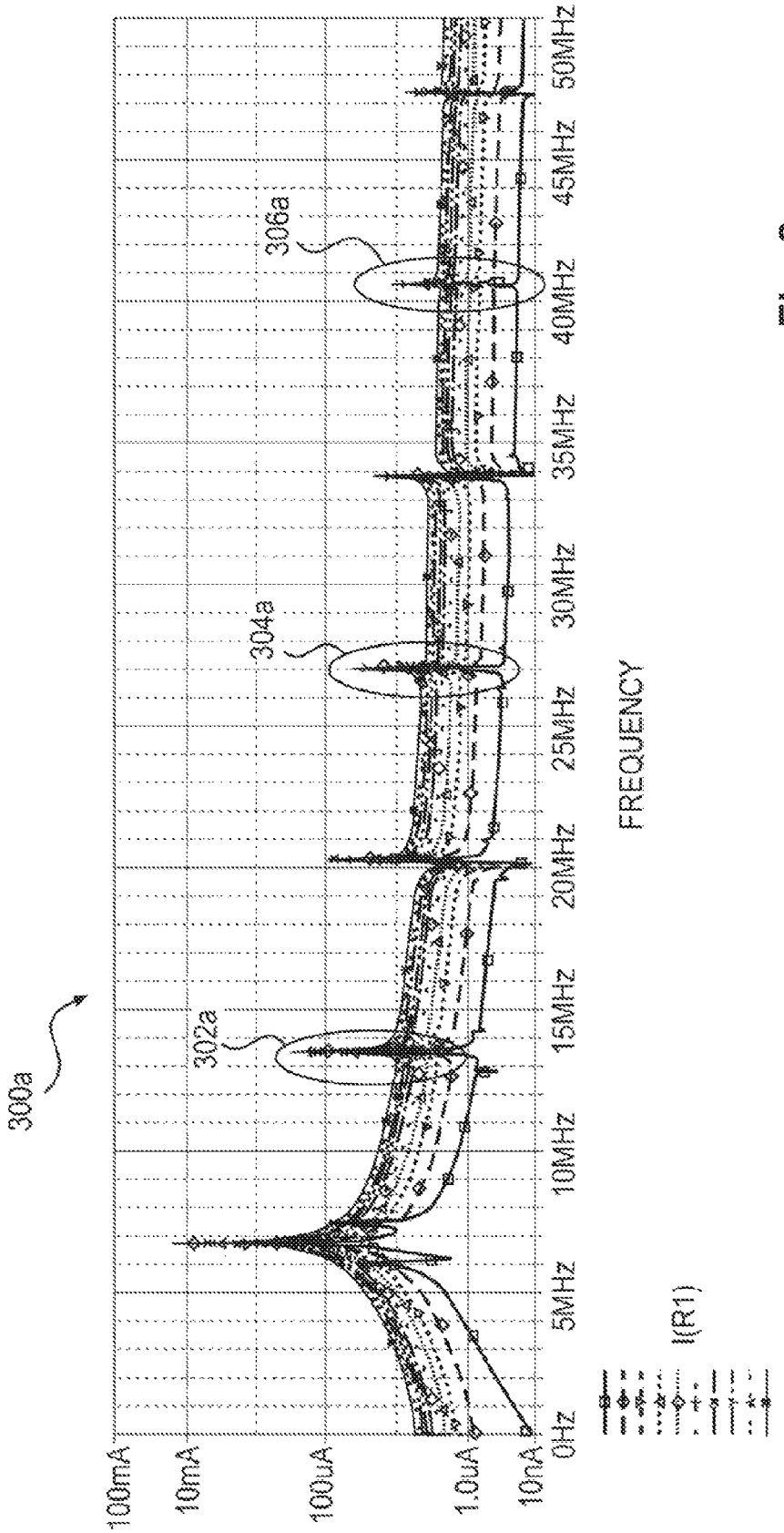

300a
302a
304a
306a
100mA
10mA
100uA
1.0uA
10nA
0Hz
5MHz
10MHz
15MHz
20MHz
25MHz
30MHz
35MHz
40MHz
45MHz
50MHz
FREQUENCY
I(R1)

Fig. 8

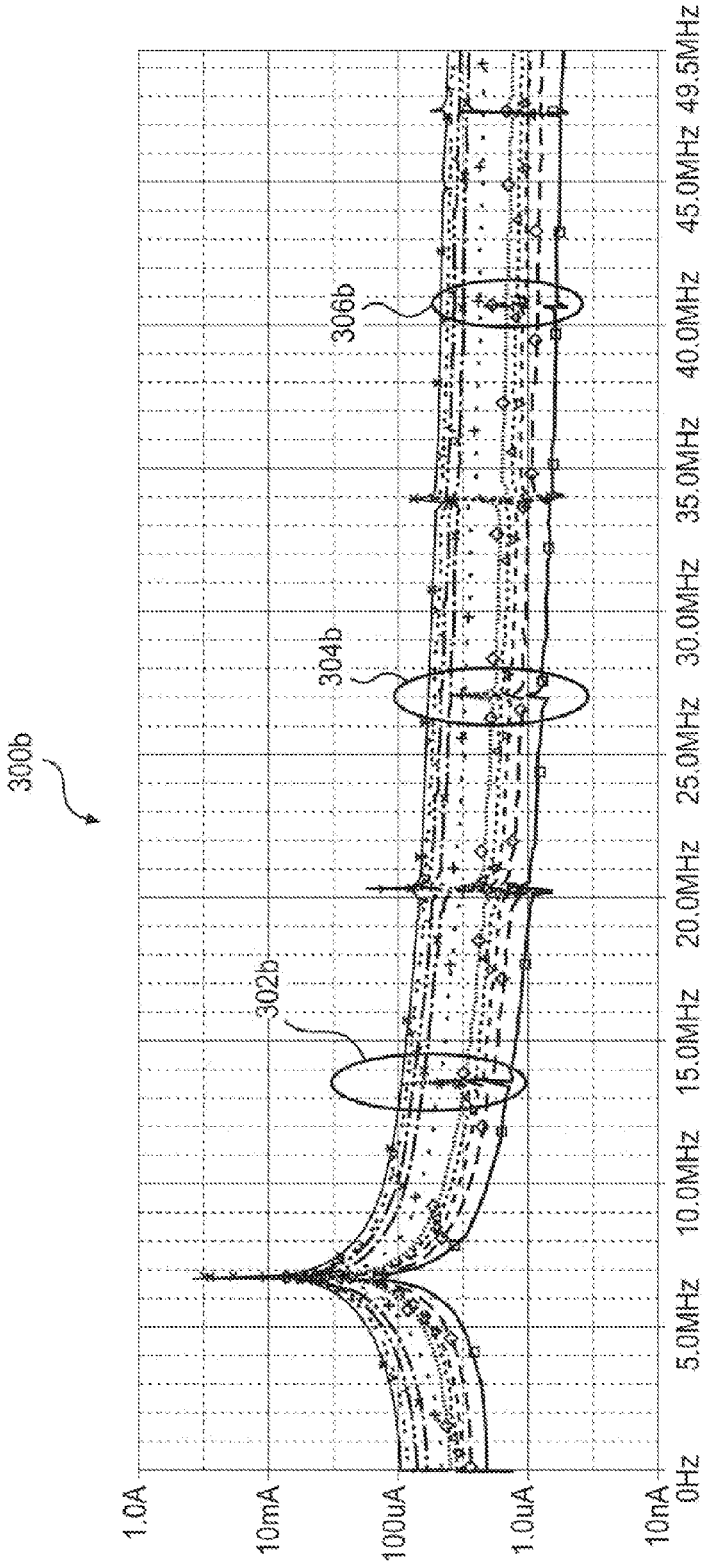

300b
302b
304b
306b
1.0A
10mA
100uA
1.0uA
10nA
0Hz
5.0MHz
10.0MHz
15.0MHz
20.0MHz
25.0MHz
30.0MHz
35.0MHz
40.0MHz
45.0MHz
49.5MHz
FREQUENCY
I(R1)

Fig. 9

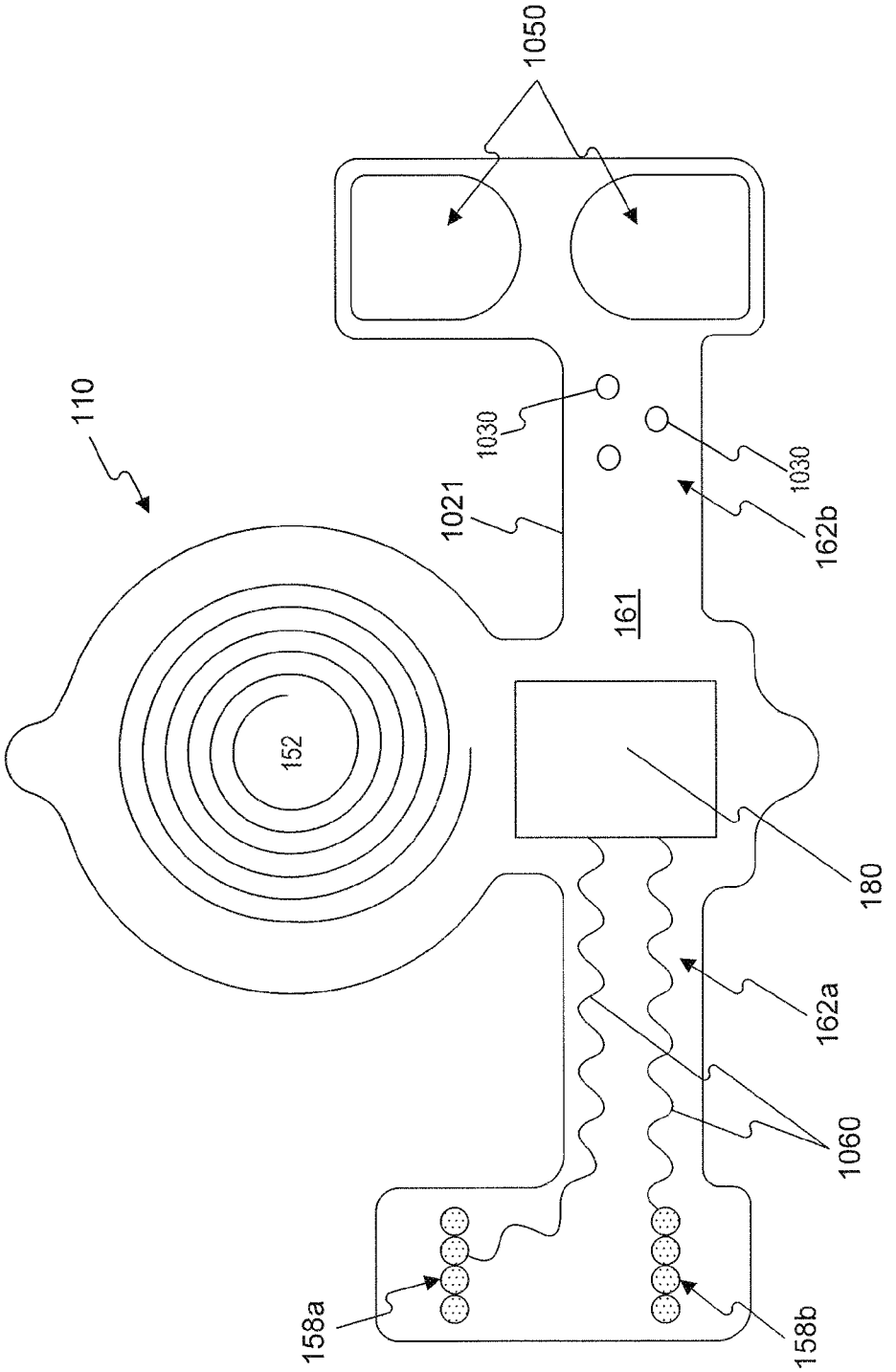


Fig. 10

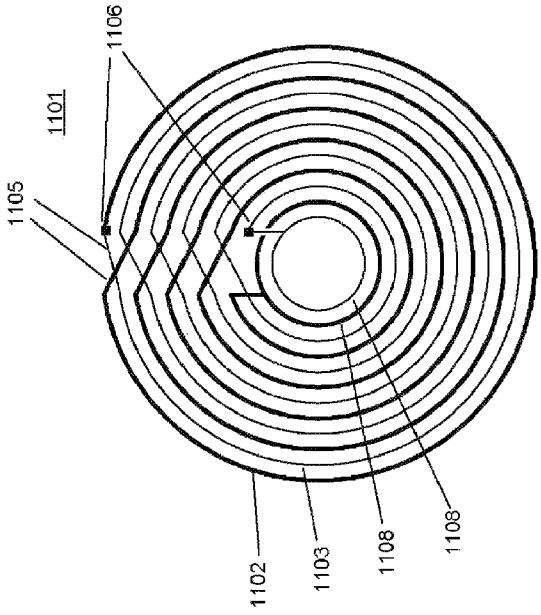


Fig. 11b

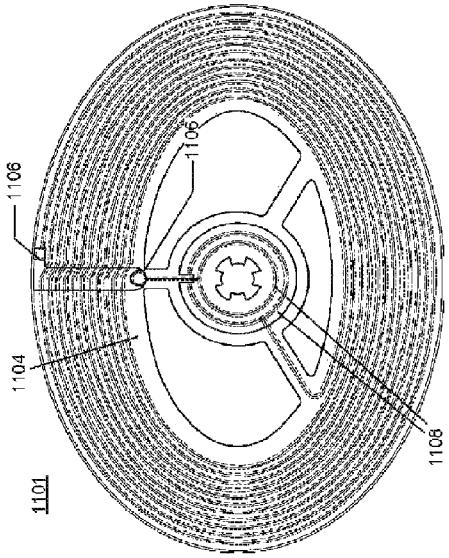


Fig. 11a

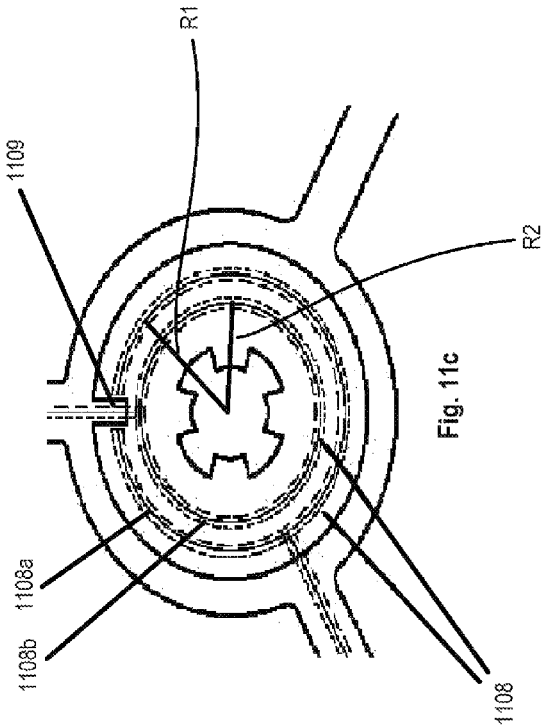


Fig. 11c

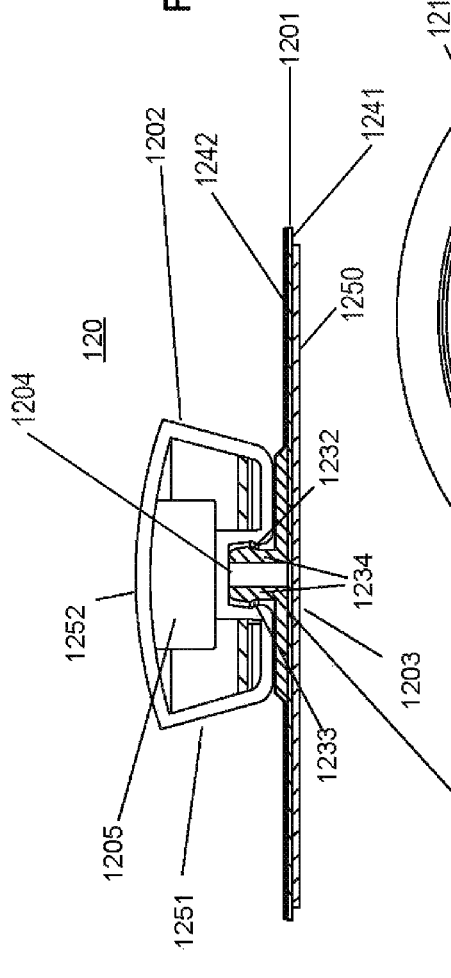


Fig. 12a

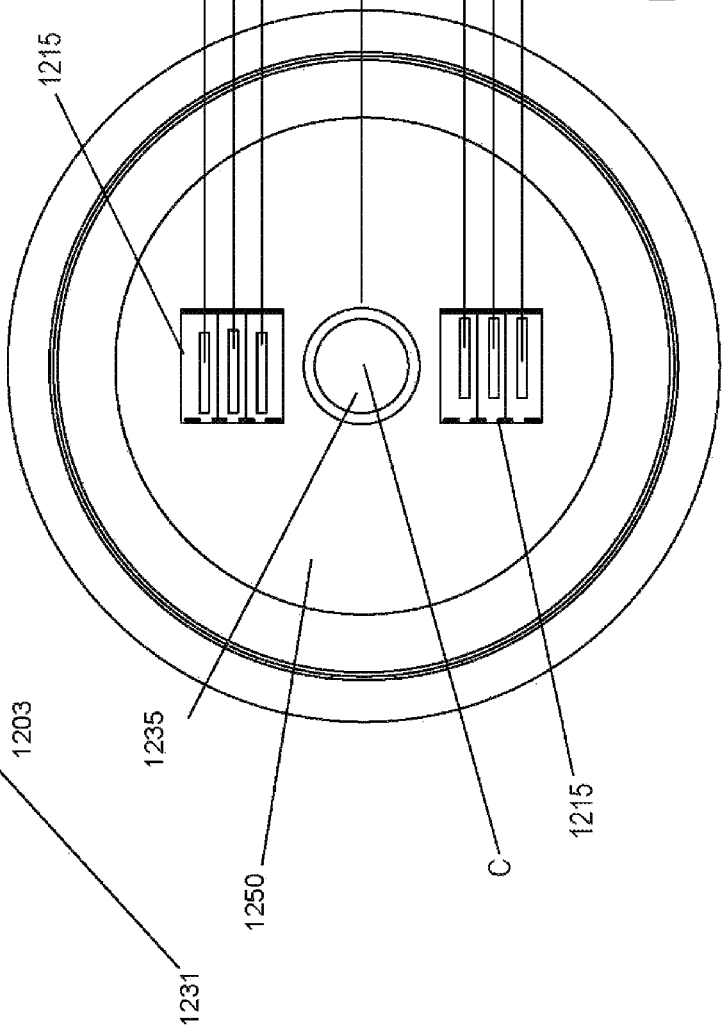
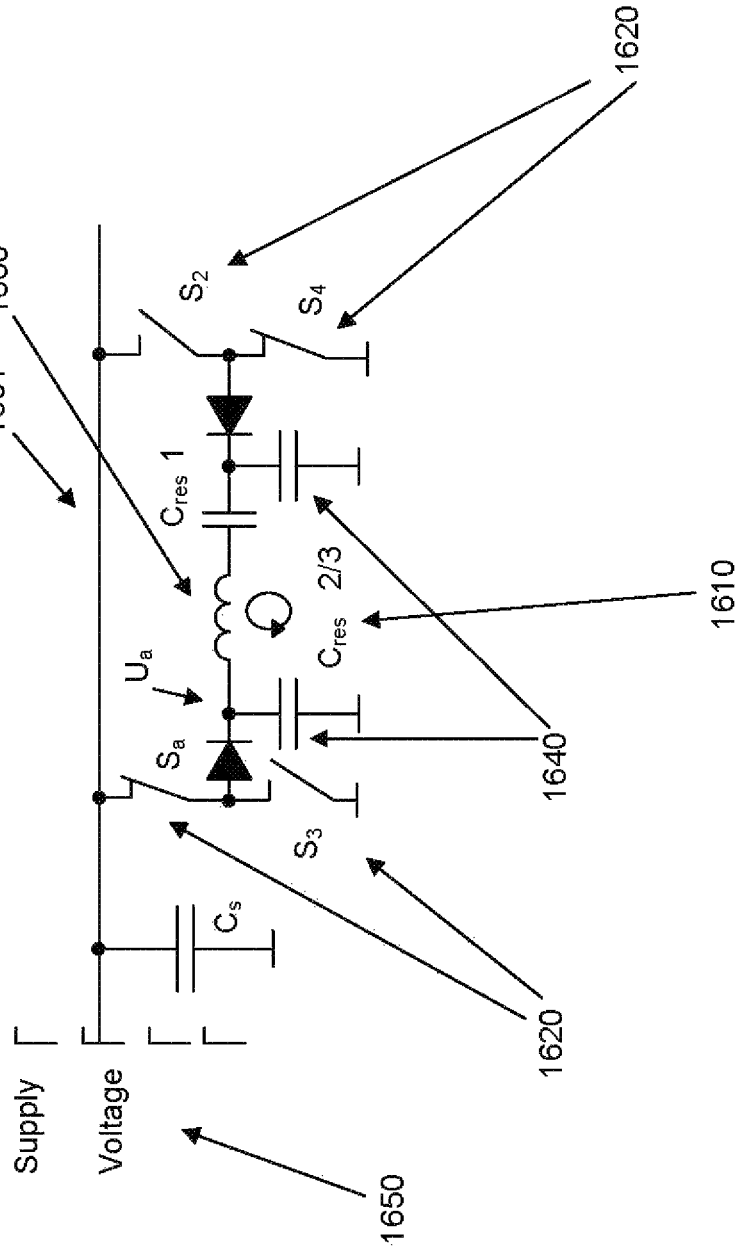


Fig. 12b

Fig. 13

Modified Class-D Type Amplifier



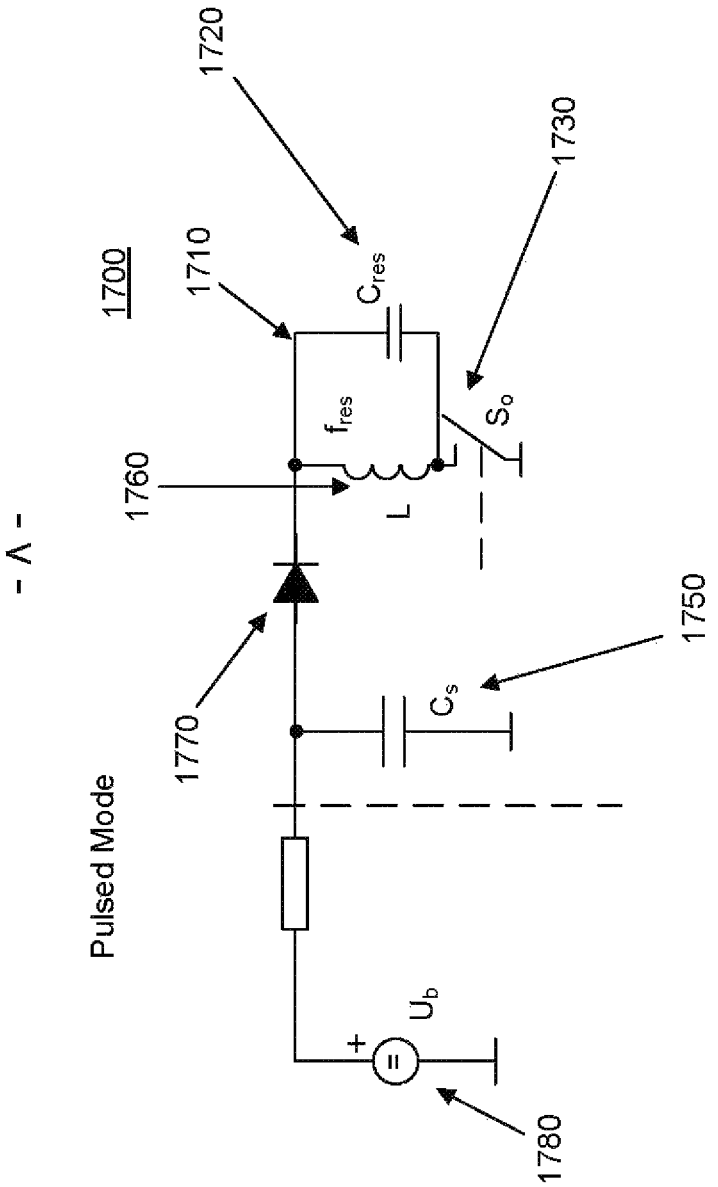

1720
1730
1700
1710
C_{res}
f_{res}
S_o
1760
L
- V -
1750
C_s
1770
Pulsed Mode
U_b
1780

Fig. 14

ELECTRICAL CONTACTS ON A MEDICAL DEVICE PATCH

RELATED APPLICATIONS

This application is a continuation of application Ser. No. 13/952,027, filed on Jul. 26, 2013, which claims the benefit of priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 61/676,327, filed Jul. 26, 2012, the entire disclosures of which are incorporated herein by reference.

TECHNICAL FIELD

Embodiments of the present disclosure generally relate to devices and methods for modulating a nerve. More particularly, embodiments of the present disclosure relate to devices and methods for modulating a nerve through the delivery of energy via an implantable electrical modulator.

BACKGROUND

Neural modulation presents the opportunity to treat many physiological conditions and disorders by interacting with the body's own natural neural processes. Neural modulation includes inhibition (e.g. blockage), stimulation, modification, regulation, or therapeutic alteration of activity, electrical or chemical, in the central, peripheral, or autonomic nervous system. By modulating the activity of the nervous system, for example through the stimulation of nerves or the blockage of nerve signals, several different goals may be achieved. Motor neurons may be stimulated at appropriate times to cause muscle contractions. Sensory neurons may be blocked, for instance to relieve pain, or stimulated, for instance to provide a signal to a subject. In other examples, modulation of the autonomic nervous system may be used to adjust various involuntary physiological parameters, such as heart rate and blood pressure. Neural modulation may provide the opportunity to treat several diseases or physiological conditions, a few examples of which are described in detail below.

Among the conditions to which neural modulation may be applied is obstructive sleep apnea (OSA). OSA is a respiratory disorder characterized by recurrent episodes of partial or complete obstruction of the upper airway during sleep. During the sleep of a person without OSA, the pharyngeal muscles relax during sleep and gradually collapse, narrowing the airway. The airway narrowing limits the effectiveness of the sleeper's breathing, causing a rise in CO_2 levels in the blood. The increase in CO_2 results in the pharyngeal muscles contracting to open the airway to restore proper breathing. The largest of the pharyngeal muscles responsible for upper airway dilation is the genioglossus muscle, which is one of several different muscles in the tongue. The genioglossus muscle is responsible for forward tongue movement and the stiffening of the anterior pharyngeal wall. In patients with OSA, the neuromuscular activity of the genioglossus muscle is decreased compared to normal individuals, accounting for insufficient response and contraction to open the airway as compared to a normal individual. This lack of response contributes to a partial or total airway obstruction, which significantly limits the effectiveness of the sleeper's breathing. In OSA patients, there are often several airway obstruction events during the night. Because of the obstruction, there is a gradual decrease of oxygen levels in the blood (hypoxemia). Hypoxemia leads to night time arousals, which may be registered by EEG, showing that the brain awakes from any stage of sleep to a short arousal. During the arousal, there is a conscious breath or gasp, which resolves the airway obstruction. An increase in sympathetic tone activity rate through the release of hormones such as epinephrine and noradrenaline also often occurs as a response to hypoxemia. As a result of the increase in sympathetic tone, the heart enlarges in an attempt to pump more blood and increase the blood pressure and heart rate, further arousing the patient. After the resolution of the apnea event, as the patient returns to sleep, the airway collapses again, leading to further arousals.

These repeated arousals, combined with repeated hypoxemia, leaves the patient sleep deprived, which leads to daytime somnolence and worsens cognitive function. This cycle can repeat itself up to hundreds of times per night in severe patients. Thus, the repeated fluctuations in and sympathetic tone and episodes of elevated blood pressure during the night evolve to high blood pressure through the entire day. Subsequently, high blood pressure and increased heart rate may cause other diseases.

Efforts for treating OSA include Continuous Positive Airway Pressure (CPAP) treatment, which requires the patient to wear a mask through which air is blown into the nostrils to keep the airway open. Other treatment options include the implantation of rigid inserts in the soft palate to provide structural support, tracheotomies, or tissue ablation.

Another condition to which neural modulation may be applied is the occurrence of migraine headaches. Pain sensation in the head is transmitted to the brain via the occipital nerve, specifically the greater occipital nerve, and the trigeminal nerve. When a subject experiences head pain, such as during a migraine headache, the inhibition of these nerves may serve to decrease or eliminate the sensation of pain.

Neural modulation may also be applied to hypertension. Blood pressure in the body is controlled via multiple feedback mechanisms. For example, baroreceptors in the carotid body in the carotid artery are sensitive to blood pressure changes within the carotid artery. The baroreceptors generate signals that are conducted to the brain via the glossopharyngeal nerve when blood pressure rises, signaling the brain to activate the body's regulation system to lower blood pressure, e.g. through changes to heart rate, and vasodilation/vasoconstriction. Conversely, parasympathetic nerve fibers on and around the renal arteries generate signals that are carried to the kidneys to initiate actions, such as salt retention and the release of angiotensin, which raise blood pressure. Modulating these nerves may provide the ability to exert some external control over blood pressure.

The foregoing are just a few examples of conditions to which neuromodulation may be of benefit, however embodiments of the invention described hereafter are not necessarily limited to treating only the above-described conditions.

SUMMARY

A device for conveying power from a location external to a subject to a location within the subject may include a flexible carrier. An adhesive may be on a first side of the carrier, and a coil of electrically conductive material may be associated with the flexible carrier. A mechanical connector may be associated with the carrier, opposite the adhesive, wherein the mechanical connector is configured to retain a housing and permit the housing to rotate relative to the flexible carrier. Additionally, at least one electrical portion may be associated with the carrier in a manner permitting electrical connection to be maintained between the flexible carrier and the housing as the housing is rotated.

In some embodiments, a device for conveying power from a location external to a subject to a location within the subject may include a housing. An electronics portion may be dis-

posed within the housing. A mechanical connector may be associated with the housing, and may be configured to retain a flexible carrier and to permit the housing to rotate relative to the flexible carrier. Additionally, at least one electrical connector may be associated with the housing in a manner permitting electrical connection to be maintained between the housing and the flexible carrier as the housing is rotated.

In some embodiments, a device for conveying power from a location external to a subject to a location within the subject may include a flexible carrier having a receiver. A coil of electrically conductive material may be associated with the flexible carrier. A housing, including a mechanical connector, may be configured to mate with the receiver and permit the housing to rotate relative to the flexible carrier. At least one electrical connector may be associated with the housing in a manner permitting electrical connection to be maintained between the housing and the flexible carrier as the housing is rotated.

Additional features of the disclosure will be set forth in part in the description that follows, and in part will be obvious from the description, or may be learned by practice of the disclosed embodiments.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the disclosure and, together with the description, serve to explain the principles of the embodiments disclosed herein.

FIG. **1** schematically illustrates an implant unit and external unit, according to an exemplary embodiment of the present disclosure.

FIG. **2** is a partially cross-sectioned side view of a subject with an implant unit and external unit, according to an exemplary embodiment of the present disclosure.

FIG. **3** schematically illustrates a system including an implant unit and an external unit, according to an exemplary embodiment of the present disclosure.

FIG. **4** is a top view of an implant unit, according to an exemplary embodiment of the present disclosure.

FIG. **5** is a top view of an alternate embodiment of an implant unit, according to an exemplary embodiment of the present disclosure.

FIG. **6** illustrates circuitry of an implant unit and an external unit, according to an exemplary embodiment of the present disclosure.

FIG. **7** illustrates a graph of quantities that may be used in determining energy delivery as a function coupling, according to an exemplary disclosed embodiment.

FIG. **8** depicts a graph illustrating non-linear harmonics.

FIG. **9** depicts a graph of quantities that may be used in determining energy delivery as a function coupling, according to an exemplary disclosed embodiment.

FIG. **10** illustrates additional features of one embodiment of implant unit **110**.

FIGS. **11***a*, **11***b*, and **11***c* illustrate a double-layer crossover antenna.

FIGS. **12***a* and **12***b* illustrate an exemplary embodiment of an external unit.

FIG. **13** depicts a self-resonant transmitter employing a modified class D amplifier.

FIG. **14** depicts a pulsed mode self-resonant transmitter.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

Reference will now be made in detail to exemplary embodiments of the present disclosure, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Embodiments of the present disclosure relate generally to a device for modulating a nerve through the delivery of energy. Nerve modulation, or neural modulation, includes inhibition (e.g. blockage), stimulation, modification, regulation, or therapeutic alteration of activity, electrical or chemical, in the central, peripheral, or autonomic nervous system. Nerve modulation may take the form of nerve stimulation, which may include providing energy to the nerve to create a voltage change sufficient for the nerve to activate, or propagate an electrical signal of its own. Nerve modulation may also take the form of nerve inhibition, which may including providing energy to the nerve sufficient to prevent the nerve from propagating electrical signals. Nerve inhibition may be performed through the constant application of energy, and may also be performed through the application of enough energy to inhibit the function of the nerve for some time after the application. Other forms of neural modulation may modify the function of a nerve, causing a heightened or lessened degree of sensitivity. As referred to herein, modulation of a nerve may include modulation of an entire nerve and/or modulation of a portion of a nerve. For example, modulation of a motor neuron may be performed to affect only those portions of the neuron that are distal of the location to which energy is applied.

In patients with OSA, for example, a primary target response of nerve stimulation may include contraction of a tongue muscle (e.g., the muscle) in order to move the tongue to a position that does not block the patient's airway. In the treatment of migraine headaches, nerve inhibition may be used to reduce or eliminate the sensation of pain. In the treatment of hypertension, neural modulation may be used to increase, decrease, eliminate or otherwise modify nerve signals generated by the body to regulate blood pressure.

While embodiments of the present disclosure may be disclosed for use in patients with specific conditions, the embodiments may be used in conjunction with any patient/portion of a body where nerve modulation may be desired. That is, in addition to use in patients with OSA, migraine headaches, or hypertension, embodiments of the present disclosure may be use in many other areas, including, but not limited to: deep brain stimulation (e.g., treatment of epilepsy, Parkinson's, and depression); cardiac pace-making, stomach muscle stimulation (e.g., treatment of obesity), back pain, incontinence, menstrual pain, and/or any other condition that may be affected by neural modulation.

FIG. **1** illustrates an implant unit and external unit, according to an exemplary embodiment of the present disclosure. An implant unit **110**, may be configured for implantation in a subject, in a location that permits it to modulate a nerve **115**. The implant unit **110** may be located in a subject such that intervening tissue **111** exists between the implant unit **110** and the nerve **115**. Intervening tissue may include muscle tissue, connective tissue, organ tissue, or any other type of biological tissue. Thus, location of implant unit **110** does not require contact with nerve **115** for effective neuromodulation. The implant unit **110** may also be located directly adjacent to nerve **115**, such that no intervening tissue **111** exists.

In treating OSA, implant unit **110** may be located on a genioglossus muscle of a patient. Such a location is suitable for modulation of the hypoglossal nerve, branches of which run inside the genioglossus muscle. Implant unit **110** may also be configured for placement in other locations. For example, migraine treatment may require subcutaneous implantation in the back of the neck, near the hairline of a

subject, or behind the ear of a subject, to modulate the greater occipital nerve and/or the trigeminal nerve. Treating hypertension may require the implantation of a neuromodulation implant intravascularly inside the renal artery or renal vein (to modulate the parasympathetic renal nerves), either unilaterally or bilaterally, inside the carotid artery or jugular vein (to modulate the glossopharyngeal nerve through the carotid baroreceptors). Alternatively or additionally, treating hypertension may require the implantation of a neuromodulation implant subcutaneously, behind the ear or in the neck, for example, to directly modulate the glossopharyngeal nerve.

External unit **120** may be configured for location external to a patient, either directly contacting, or close to the skin **112** of the patient. External unit **120** may be configured to be affixed to the patient, for example, by adhering to the skin **112** of the patient, or through a band or other device configured to hold external unit **120** in place. Adherence to the skin of external unit **120** may occur such that it is in the vicinity of the location of implant unit **110**.

FIG. **2** illustrates an exemplary embodiment of a neuromodulation system for delivering energy in a patient **100** with OSA. The system may include an external unit **120** that may be configured for location external to the patient. As illustrated in FIG. **2**, external unit **120** may be configured to be affixed to the patient **100**. FIG. **2** illustrates that in a patient **100** with OSA, the external unit **120** may be configured for placement underneath the patient's chin and/or on the front of patient's neck. The suitability of placement locations may be determined by communication between external unit **120** and implant unit **110**, discussed in greater detail below. In alternate embodiments, for the treatment of conditions other than OSA, the external unit may be configured to be affixed anywhere suitable on a patient, such as the back of a patient's neck, i.e. for communication with a migraine treatment implant unit, on the outer portion of a patient's abdomen, i.e. for communication with a stomach modulating implant unit, on a patient's back, i.e. for communication with a renal artery modulating implant unit, and/or on any other suitable external location on a patient's skin, depending on the requirements of a particular application.

External unit **120** may further be configured to be affixed to an alternative location proximate to the patient. For example, in one embodiment, the external unit may be configured to fixedly or removably adhere to a strap or a band that may be configured to wrap around a part of a patient's body. Alternatively, or in addition, the external unit may be configured to remain in a desired location external to the patient's body without adhering to that location.

The external unit **120** may include a housing. The housing may include any suitable container configured for retaining components. In addition, while the external unit is illustrated schematically in FIG. **2**, the housing may be any suitable size and/or shape and may be rigid or flexible. Non-limiting examples of housings for the external unit **100** include one or more of patches, buttons, or other receptacles having varying shapes and dimensions and constructed of any suitable material. In one embodiment, for example, the housing may include a flexible material such that the external unit may be configured to conform to a desired location. For example, as illustrated in FIG. **2**, the external unit may include a skin patch, which, in turn, may include a flexible substrate. The material of the flexible substrate may include, but is not limited to, plastic, silicone, woven natural fibers, and other suitable polymers, copolymers, and combinations thereof. Any portion of external unit **120** may be flexible or rigid, depending on the requirements of a particular application.

As previously discussed, in some embodiments external unit **120** may be configured to adhere to a desired location. Accordingly, in some embodiments, at least one side of the housing may include an adhesive material. The adhesive material may include a biocompatible material and may allow for a patient to adhere the external unit to the desired location and remove the external unit upon completion of use. The adhesive may be configured for single or multiple uses of the external unit. Suitable adhesive materials may include, but are not limited to biocompatible glues, starches, elastomers, thermoplastics, and emulsions.

FIG. **3** schematically illustrates a system including external unit **120** and an implant unit **110**. In some embodiments, internal unit **110** may be configured as a unit to be implanted into the body of a patient, and external unit **120** may be configured to send signals to and/or receive signals from implant unit **110**.

As shown in FIG. **3**, various components may be included within a housing of external unit **120** or otherwise associated with external unit **120**. As illustrated in FIG. **3**, at least one processor **144** may be associated with external unit **120**. For example, the at least one processor **144** may be located within the housing of external unit **120**. In alternative embodiments, the at least one processor may be configured for wired or wireless communication with the external unit from a location external to the housing.

The at least one processor may include any electric circuit that may be configured to perform a logic operation on at least one input variable. The at least one processor may therefore include one or more integrated circuits, microchips, microcontrollers, and microprocessors, which may be all or part of a central processing unit (CPU), a digital signal processor (DSP), a field programmable gate array (FPGA), or any other circuit known to those skilled in the art that may be suitable for executing instructions or performing logic operations.

FIG. **3** illustrates that the external unit **120** may further be associated with a power source **140**. The power source may be removably couplable to the external unit at an exterior location relative to external unit. Alternatively, as shown in FIG. **3**, power source **140** may be permanently or removably coupled to a location within external unit **120**. The power source may further include any suitable source of power configured to be in electrical communication with the processor. In one embodiment, for example the power source **140** may include a battery.

The power source may be configured to power various components within the external unit **120**. As illustrated in FIG. **3**, power source **140** may be configured to provide power to the processor **144**. In addition, the power source **140** may be configured to provide power to a signal source **142** and a feedback circuit **148**. The signal source **142** may be in communication with the processor **144** and may include any device configured to generate a signal (e.g., a sinusoidal signal, square wave, triangle wave, microwave, radio-frequency (RF) signal, or any other type of electromagnetic signal). Signal source **142** may include, but is not limited to, a waveform generator that may be configured to generate alternating current (AC) signals and/or direct current (DC) signals. In one embodiment, for example, signal source **142** may be configured to generate an AC signal for transmission to one or more other components. Signal source **142** may be configured to generate a signal of any suitable frequency. In some embodiments, signal source **142** may be configured to generate a signal having a frequency of from about 6.5 MHz to about 13.6 MHz. In additional embodiments, signal source **142** may be configured to generate a signal having a frequency of from about 7.4 to about 8.8 MHz. In further embodiments, signal

source **142** may generate a signal having a frequency as low as 90 kHz or as high as 28 MHz.

Signal source **142** may be configured for direct or indirect electrical communication with an amplifier **146**. The amplifier may include any suitable device configured to amplify one or more signals generated from signal source **142**. Amplifier **146** may include one or more of various types of amplification devices, including, for example, transistor based devices, operational amplifiers, RF amplifiers, power amplifiers, or any other type of device that can increase the gain associated with one or more aspects of a signal. The amplifier may further be configured to output the amplified signals to one or more components within external unit **120**.

Feedback circuit **148**, as shown in FIG. **3**, may be in electrical communication with various components of external unit **120**. For example, feedback circuit **148** may be in direct or indirect electrical contact with processor **144** and a primary antenna **150**. In some embodiments, feedback circuit **148** may include, for example, a signal analyzer or a detector.

The external unit **120** may additionally include primary antenna **150**. As shown in FIG. **3**, primary antenna **150** may be configured as part of a circuit within external unit **120** and may be coupled either directly or indirectly to various components in external unit **120**. For example, as shown in FIG. **3**, primary antenna **150** may be configured for communication with the amplifier **146**.

The primary antenna **150** may include any conductive structure that may be configured to create an electromagnetic field. The primary antenna **150** may further be of any suitable size, shape, and/or configuration. The size, shape, and/or configuration may be determined by the size of the patient, the placement location of the implant unit, the size and/or shape of the implant unit, the amount of energy required to modulate a nerve, a location of a nerve to be modulated, the type of receiving electronics present on the implant unit, etc. The primary antenna may include any suitable antenna known to those skilled in the art that may be configured to send and/or receive signals. Suitable antennas may include, but are not limited to, a long-wire antenna, a patch antenna, a helical antenna, etc. In one embodiment, for example, as illustrated in FIG. **3**, primary antenna **150** may include a coil antenna. Such a coil antenna may be made from any suitable conductive material and may be configured to include any suitable arrangement of conductive coils (e.g., diameter, number of coils, layout of coils, etc.). A coil antenna suitable for use as primary antenna **150** may have a diameter of between about 1 cm and 10 cm, and may be circular or oval shaped. In some embodiments, a coil antenna may have a diameter between 5 cm and 7 cm, and may be oval shaped. A coil antenna suitable for use as primary antenna **150** may have any number of windings, e.g. 4, 8, 12, or more. A coil antenna suitable for use as primary antenna **150** may have a wire diameter between about 0.01 mm and 2 mm. These antenna parameters are exemplary only, and may be adjusted above or below the ranges given to achieve suitable results.

As noted, implant unit **110** may be configured to be implanted in a patient's body (e.g., beneath the patient's skin). FIG. **2** illustrates that the implant unit **110** may be configured to be implanted for modulation of a nerve associated with a muscle of the subject's tongue **130**. Modulating a nerve associated with a muscle of the subject's tongue **130** may include stimulation to cause a muscle contraction. In further embodiments, the implant unit may be configured to be placed in conjunction with any nerve that one may desire to modulate. For example, modulation of the occipital nerve, the greater occipital nerve, and/or the trigeminal nerve may be useful for treating pain sensation in the head, such as that from migraines. Modulation of parasympathetic nerve fibers on and around the renal arteries (i.e. the renal nerves), the vagus nerve, and/or the glossopharyngeal nerve may be useful for treating hypertension. Additionally, any nerve of the peripheral nervous system (both spinal and cranial), including motor neurons, sensory neurons, sympathetic neurons and parasympathetic neurons, may be modulated to achieve a desired effect.

Implant unit **110** may be formed of any materials suitable for implantation into the body of a patient. In some embodiments, implant unit **110** may include a flexible carrier **161** (FIG. **4**) including a flexible, biocompatible material. Such materials may include, for example, silicone, polyimides, phenyltrimethoxysilane (PTMS), polymethyl methacrylate (PMMA), Parylene C, polyimide, liquid polyimide, laminated polyimide, black epoxy, polyether ether ketone (PEEK), Liquid Crystal Polymer (LCP), Kapton, etc. Implant unit **110** may further include circuitry including conductive materials, such as gold, platinum, titanium, or any other biocompatible conductive material or combination of materials. Implant unit **110** and flexible carrier **161** may also be fabricated with a thickness suitable for implantation under a patient's skin. Implant **110** may have thickness of less than about 4 mm or less than about 2 mm. Other components that may be included in or otherwise associated with the implant unit are illustrated in FIG. **3**. For example, implant unit **110** may include a harmonics modifier circuit **154**, non-linear circuit components, such as diode **156**, and a secondary antenna **152** mounted onto or integrated with flexible carrier **161**. Harmonics modifier circuit **154** may include any electrical components configured to non-linearly alter the harmonics generated in implant unit **110**. Similar to the primary antenna **150**, the secondary antenna **152** may include any suitable antenna known to those skilled in the art that may be configured to send and/or receive signals. The secondary antenna may include any suitable size, shape, and/or configuration. The size, shape and/or configuration may be determined by the size of the patient, the placement location of the implant unit, the amount of energy required to modulate the nerve, etc. Suitable antennas may include, but are not limited to, a long-wire antenna, a patch antenna, a helical antenna, etc. In some embodiments, for example, secondary antenna **152** may include a coil antenna having a circular shape (see also FIG. **4**) or oval shape. Such a coil antenna may be made from any suitable conductive material and may be configured to include any suitable arrangement of conductive coils (e.g., diameter, number of coils, layout of coils, etc.). A coil antenna suitable for use as secondary antenna **152** may have a diameter of between about 5 mm and 30 mm, and may be circular or oval shaped. A coil antenna suitable for use as secondary antenna **152** may have any number of windings, e.g. 4, 15, 20, 30, or 50. A coil antenna suitable for use as secondary antenna **152** may have a wire diameter between about 0.001 mm and 1 mm. These antenna parameters are exemplary only, and may be adjusted above or below the ranges given to achieve suitable results. FIGS. **11***a* and **11***b* illustrate a double-layer crossover antenna **1101** suitable for use as either primary antenna **150** or secondary antenna **152**. While a double-layer crossover antenna is shown and described, other antenna configurations may be suitable for primary antenna **150** and/or secondary antenna **152**. For example, single layer antennas may be used where antenna components (e.g., coils) are arranged in a single layer, e.g., either on or within a dielectric or insulating material. Also, while a crossover pattern is shown, other patterns may also be suitable. For example, in some embodiments, a wire associated with primary antenna **150** and/or secondary antenna **152** may include a pattern of

traces of progressively decreasing dimension. In the case of traces arranged in coils, for example, each loop may include rings of progressively decreasing diameter to create a pattern that spirals inwardly. A similar approach may be viable using traces of other shapes as well.

Returning to FIG. **11***a*, this figure illustrates a single coil of double-layer crossover antenna **1101**, while FIG. **11***b* illustrates two layers of double layer crossover antenna **1101**. Antenna **1101** may include a first coil of wire **1102** arranged on a first side of a dielectric carrier **1104** and a second coil of wire **1103** on a second side of a dielectric carrier **1104**.

Arranging the antenna coils in a double layer may serve to increase the transmission range of the antenna without increasing the size of the antenna. Such an arrangement, however, may also serve to increase capacitance between the wires of each coil. In each wire coil, an amount of parasitic capacitance between wires may partially depend on the distance each wire is from its neighbor. In a single layer coil, capacitance may be generated between each loop of the coil and its neighbors to either side. Thus, more compact coils may generate more parasitic capacitance. When a second layer coil is added, additional capacitance may then be generated between the wires of the first coil and the wires of the second coil. This additional capacitance may be further increased if corresponding loops of the first and second coils have the same or similar diameters, and/or if a dielectric carrier separating the loops is made very thin. Increased parasitic capacitance in an antenna may serve to alter characteristics, such as resonant frequency, of the antenna in unpredictable amounts based on manufacturing specifications. Additionally, resonant frequency drift, caused for example by moisture incursion or antenna flexing, may be increased by the presence of increased parasitic capacitance. Thus, in order to decrease variability in the manufactured product, it may be advantageous to reduce the levels of parasitic capacitance in a dual layer antenna.

FIG. **11***b* illustrates a double layer crossover antenna **1101** which may serve to reduce the parasitic capacitance in a manufactured antenna. As illustrated in FIG. **11***b*, a first coil of wire **1102** is concentrically offset from a second coil of wire **1103**. In contrast to a configuration where each loop of a first coil **1102** has the same diameter as corresponding loop of the second coil **1103**, concentrically offsetting corresponding loops of each wire coil serves to increase the distance between a single loop of the first coil **1102** with a corresponding loop of the second coil **1103**. This increased distance, in turn, may decrease the parasitic wire-to-wire capacitance between loops of first coil **1102** and corresponding loops of second coil **1103**. This configuration may be particularly advantageous in reducing parasitic capacitance in a situation where a dielectric carrier **1104** is thin enough such that the concentric distance by which each coil is offset is relatively large compared to the thickness of the dielectric carrier **1104**. For example, in a situation where a dielectric carrier is 0.5 mm thick, a concentric offset of 0.5 mm or more may produce a large change in parasitic capacitance. In contrast, in a situation where a dielectric carrier is 5 mm thick, a concentric offset of 0.5 mm may produce a smaller change in parasitic capacitance. The concentric offset between a first coil **1102** and a second coil **1103** may be achieved, for example, by a plurality of electrical trace steps **1105** that offset each loop of the coils from each preceding loop. Electrical trace steps **1105** on a first side of dielectric carrier **1104** cross over electrical trace steps **1105** on a second side of dielectric carrier **1104**, thus providing the crossover feature of double-layer crossover antenna **1101**.

In additional embodiments, double layer crossover antenna **1101** may include openings **1106** in dielectric carrier **1104** to facilitate the electrical connection of first and second coils **1102**, **1103**, For example, one or more conductive wires, vias, traces, etc. may extend through openings **1106** in dielectric carrier **1104** in order to establish electrical connectivity between the first and second coils **1102**, **1103**. First and second coils **1102**, **1103** of double layer crossover antenna **1101** may also include exposed electrical portions **1108** configured to electrically connect with a connector of a device housing that may be coupled to antenna **1101**. Exposed electrical portions **1108** may be configured so as to maintain electrical contact with the connector of a device housing independent of the axial orientation of the connection, as discussed further below.

As shown in FIG. **11***c*, exposed electrical portions **1108** may be configured in a pattern suitable for maintaining electrical contact with corresponding electrodes on an external unit **120**, for example. In some embodiments, exposed electrical portions **1108** may be arranged in or may comprise continuous or discontinuous patterns of conductive material associated with carrier **1104**. For example, exposed electrical portions **1108** may be arranged in continuous or discontinuous circles, ellipses, polygons, or any other suitable shape. In some embodiments, exposed electrical portions **1108** may include a first exposed electrical portion **1108***a*, forming a discontinuous circle, and a second exposed electrical portion **1108***b*, forming a continuous circle and located inside first exposed electrical portion **1108***a*. In some embodiments, first electrical portions **1108***a* may form an arc shape. Exposed electrical portion **1108** may include a plurality of first and second electrical portions **1108***a*, **1108***b* (respectively), for example, 1, 2, 4, or 5 of each. Additionally, exposed electrical portion **1108** may include an unequal number of first exposed electrical portions **1108***a* and second exposed electrical portions **1108***b*. For example, a greater number of first exposed electrical portions **1108***a* may be included as compared to second exposed electrical portions **1108***b*.

First exposed electrical portion **1108***a* may form a C-shape or U-shape configuration, providing a space **1109** between open ends. As shown in FIG. **11***c*, space **1109** may be configured for an electrical trace to pass through without contacting first exposed electrical portion **1108***a*. For example, space **1109** may allow the electrical trace to connect with second exposed electrical portion **1108***b*, or to other components located within the circle of first exposed electrical portion **1108***a*.

FIG. **11***c* illustrates an exposed electrical portion **1108** with substantially circular first and second exposed electrical portions **1108***a*, **1108***b*. However, it is further contemplated that other shapes may be utilized, for example, elliptical, triangular, square, etc. Additionally, although antenna **1101** is shown in FIG. **11***a* with substantially elliptical coils, other shapes, such as circular, triangular, square, etc., may be also be used in different embodiments. Elliptical coils may facilitate placement of external unit **120** in certain areas (e.g., under the chin of a subject) while maintaining desirable electrical performance characteristics.

FIGS. **12***a* and **12***b* illustrate an exemplary embodiment of external unit **120**, including features that may be found in any combination in other embodiments. FIG. **12***a* illustrates a side view of external unit **120**, depicting carrier **1201** and electronics housing **1202**.

Housing **1202** may be configured to contain various electrical and mechanical components, as discussed above with respect to FIG. **3**. Housing **1202** may include a bottom surface **1250**, a top surface **1252**, and at least one sidewall **1251**. When configured in a generally cylindrical arrangement,

sidewall **1251** may be a continuous surface. Bottom surface **1250** may be configured to contact carrier **1201**.

Carrier **1201** may include a skin patch configured for adherence to the skin of a subject, and having a first side **1241** and a second side **1242**. Carrier **1201** may be flexible or rigid, or may have flexible portions and rigid portions. A securing element **1250** may be disposed on the first side **1241** of carrier **1201**. Securing element **1250** may include a chemical-based agent (e.g., an adhesive material) or mechanical structures configured to secure carrier **1201** to a patient (e.g., to the patient's skin). In some embodiments, securing element **1240** may include an adhesive, a bonding material, a strap, or any suitable fastener. As shown in FIG. **12***a*, securing element **150** may be disposed along the entire length of first side **1241** or along a portion of first side. For example, securing element **1250** may only be disposed along flexible portions of carrier **1201**.

Carrier **1201** and may include primary antenna **150**, for example, a double-layer crossover antenna **1101** such as that illustrated in FIGS. **11***a* and **11***b*. Carrier **1201** may also include power source **140**, such as a paper battery, thin film battery, or other type of substantially flat and/or flexible battery. Carrier **1201** may also include any other type of battery or power source.

Carrier **1201** may also include a connector **1203** configured for selectively or removably connecting carrier **1201** to electronics housing **1202**. Connector **1203** may include a mechanical or electrical connection. For example, connector **1203** may include a protrusion extending or protruding away from second side **1242**. As shown in FIG. **12***a*, connector **1203** may form a rod-like extension **1234** configured to mate with a receiver **1204** in electronics housing **1202**. Receiver **1204** may include a recess or depression in electronics housing **1202**. In some embodiments, connector **1203** and receive **1204** may form an interference fit. One or more detents **1232** on connector **1203** may engage one or more detent engagement portions **1233** on electronics housing **1202** to secure connector **1203** to electronics housing **1202**. Alternatively, connector **1203** may form a recess, for example opening **1235** as shown in FIG. **12***b*. Opening **1235** may be configured to engage one or more securing means on electronics housing **1202** to secure carrier **1201** to electronics housing.

Connector **1203** may include various configurations and dimensions. For example, connector **1203** may be configured as a non-pouch connector, configured to provide a selective connection to electronics housing **1204** without the substantial use of concave feature. Connector **1203** may include, for example a peg, and may have flexible arms. Connector **1203** may further include a magnetic connection, a velcro connection, and/or a snap dome connection. Connector **1203** may also include a locating feature, configured to locate electronics housing **1202** at a specific height, axial location, and/or axial orientation with respect to carrier **1201**. A locating feature of connector **1203** may further include pegs, rings, boxes, ellipses, bumps, etc.

Connector **1203** may be centered on carrier **1201**, may be offset from the center by a predetermined amount, or may be provided at any other suitable location of carrier **1201**. Multiple connectors **1203** may be provided on carrier **1201**. Additionally, connector **1203** may be removable from electronics housing. In some embodiments, connector **1203** may be configured such that removal from electronics housing **1202** may cause breakage of connector **1203**. This may prevent re-use of carrier **1201**, which may be desirable when carrier **1201** loses efficacy through continued use.

Electronics housing **1202** is illustrated in side view in FIG. **12***a* and in a bottom view in FIG. **12***b*. Electronics housing **1202** may be disposed on second side **1242** of carrier **1201**, and may include electronics portion **1205**, arranged inside electronics housing **1202** in any manner that is suitable. Electronics portion **1205** may include various components, further discussed below, of external unit **120**. For example, electronics portion **1205** may include any combination of at least one processor **144** associated with external unit **120**, power source **140**, such as a battery, primary antenna **150**, and an electrical circuit **170** (as shown in FIG. **6**). Electronics portion **1205** may also include any other component described herein as associated with external unit **120**. Additional components may also be recognized by those of skill in the art.

Electronics housing **1202** may include at least one electrical connector **1210**, **1211**, **1212**. Electrical connectors **1210**, **1211**, **1212** may be arranged within pairs of electrical contacts **1215**, as shown in FIG. **12***b*, or with any other number of electrical contacts. The pair of electrical contacts **1215** of each electrical connector **1210**, **1211**, **1212** may be continuously electrically connected with each other inside of housing **1202**, such that the pair of electrical contacts **1215** represents a single connection point to a circuit. In such a configuration, it is only necessary that one of the electrical contacts within a pair be connected to the circuit. Electrical connectors **1210**, **1211**, **1212** may thus include redundant electrical contacts. The electrical contacts of each electrical connector **1210**, **1211**, **1212** may also represent opposite ends of a circuit, for example, the positive and negative ends of a battery charging circuit.

In an exemplary embodiment, electronics housing **1202** and carrier **1201** may be configured to maintain electrical contact independent of an axial orientation of housing **1202** with respect to carrier **1201**. Therefore, when housing **1202** is mated with and secured to carrier **1201**, for example, through connector **1203** and receiver **1204**, housing **1202** may be configured to rotate with respect to carrier **1201** while maintaining electrical contact between housing **1202** and carrier **1201**. Housing **1202** may be configured to rotate a predetermined degree of rotation while maintaining electrical contact. The predetermined degree of rotation may include, for example, about 360 degrees, more than about 360 degrees, or an angle less than 360 degrees (e.g. about 180 degrees, about 90 degrees, or about 45 degrees). Additionally, housing **1202** may be configured to rotate upwards or downwards with respect to carrier **1201**. For example, a left side of sidewall **1251** may rotate upward and away from carrier **1201** while a right side of sidewall **1251** may rotate downward and toward carrier **1201**, while still maintaining electrical contact between housing **1202** and carrier **1201**. It is further contemplated that carrier **1201** may be configured to rotate with respect to housing **1201**.

Rotation of housing **1201** and/or carrier **1201**, while maintaining electrical contact between the components, may be accomplished through connectors **1210**, **1211**, **1212** on housing **1202** and exposed electrical portions **1108** on carrier **1201**. As shown in FIG. **12***b*, electrical connectors **1210**, **1211**, and **1212** may be configured so as to maintain electrical contact with exposed electrical portions **1108**, on carrier **1201**, independent of an axial orientation of electronics housing **1202**. Connection between any or all of electrical connectors **1210**, **1211**, **1212** and exposed electrical portions **1108** may thus be established and maintained irrespective of relative axial positions of carrier **1201** and housing **1202**. Thus, when connector **1203** is mated with receiver **1204**, housing **1202** may rotate with respect to carrier **1201** without interrupting electrical contact between at least one of electrical connectors **1210**, **1211**, **1212** and exposed electrical portions **1108**.

Electrical connectors **1210**, **1211**, **1212**, may be arranged in a predetermined pattern with respect to exposed electrical portions **1108** to achieve the axial orientation independence of housing **1202** and carrier **1201**. For example, the pairs of electrical contacts **1215** may be disposed equidistant from a center C of bottom surface **1250** of housing **1202** (FIG. **12***b*). In some embodiments, the pairs of electrical contacts **1215** may be disposed equidistant from a center of receiver **1204**. This arrangement of the pairs of electrical contacts **1215** may allow electrical connectors **1210**, **1211**, **1212** to be equally spaced from the center as electrical connectors **1210**, **1211**, **1212** on a corresponding electrical contact **1215**. For example, as shown in FIG. **12***b*, an outer connector **1210** on a first electrical contact **1215** is disposed at a distance from the center C equal to a distance from the center C where outer connector **1210** on a second (or other) electrical contact **1215** is located. In such a configuration, as housing **1202** rotates relative to carrier **1201**, at least one electrode from one or more of the pairs of electrodes **1210**, pairs **1211**, and pairs **1212** may remain in electrical contact with respective electrodes or electrical portions associated with housing **1202**.

The electrical connectors **1210**, **1211**, **1212** may be disposed a distance from center C substantially equal to the radius of a corresponding exposed electrical portion **1108**. For example, electrical connector **1210** may be disposed a distance equal to the radius R**1** of first exposed electrical portion **1108***a* (FIG. **11***c*). Therefore, electrical connector **1210** may be disposed substantially directly over first exposed electrical portion **1108***a*. Additionally, electrical connector **1211** may be disposed a distance equal to the radius R**2** of second exposed electrical portion **1108***b*, and therefore substantially over second exposed electrical portion **1108***b*. Each of electrical connectors **1210**, **1211**, **1212** may make contact with its corresponding exposed electrical portion **1108**. Therefore, first exposed electrical portion **1108***a* may be in electrical contact with electrical connector **1210**, and second exposed electrical portion **1108***b* may be in electrical contact with connector **1211**. When exposed electrical portions **1108** include a discontinuous circle, such as first exposed electrical portion **1108***a*, thereby substantially preventing electrical contact between first exposed electrical portion **1108***a* and its corresponding electrical connector **1210**, electrical contact between housing **1202** and carrier **1201** may still be maintained between second exposed electrical portion **1108***b* and electrical connector **1211**.

In other embodiments, electrical connectors **1210**, **1211**, **1212** may make contact with an offset exposed electrical portion **1108**. For example, continuing the above example, electrical connector **1212** may be offset from second electrical portion **1108***b*, but still configured to make electrical contact with second electrical portion **1108***b*. Therefore, when housing **1202** includes more electrical connectors than there are exposed electrical portions **1108**, each electrical connector may be in continuous electrical contact with carrier **1201**. Housing **1202** may include any number of electrical connectors with regard to the number of exposed electrical portions **1108** on carrier **1201**.

When in electrical contact with electrical connectors **1210**, **1211**, **1212**, exposed electrical portions **1108** may also be electrically connected to the electrical components contained in electronics portion **1205**. However, in some embodiments, electrical connectors **1210**, **1211**, **1212** may be used in configurations not involving contact with electrodes on carrier **1201**. In such embodiments, for example, electrical connectors **1210**, **1211**, **1212** may be configured to function as opposite ends of a battery charging circuit and may be configured and used to charge a battery contained in electronics portion **1205**.

As shown in FIG. **12***b*, electrical connectors **1210**, **1211**, **1212** are illustrated as substantially rectangular. However, electrical connectors **1210**, **1211**, **1212** may include a variety of shapes and configurations. For example, these electrical connectors may be circular, elliptical, triangular, square, etc. In some embodiments, electrical connectors **1210**, **1211**, **1212** may be configured as continuous or discontinuous patterns (e.g., circular patterns or patterns of any other suitable shape). It is further contemplated that housing **1202** may include any suitable number of connectors.

In an additional embodiment consistent with the present disclosure, electronics housing **1202** may include an activator chip. Processor **144** may be configured to activate when at least one of electrical connectors **1210**, **1211**, **1212** contact exposed electrical portions **1108** included in carrier **1201**. In this manner, an electronics housing **1202** may be charged and left dormant for many days prior to activation. Simply connecting electronics housing **1202** to carrier **1201** (and inducing contact between an electrical connector **1210**, **1211**, **1212** and an electrical portion **1108**) may cause the processor to activate. Upon activation, processor **144** may be configured to enter a specific mode of operation, such as a calibration mode (for calibrating the processor after placement of the carrier on the skin), a placement mode (for assisting a user to properly place the carrier on the skin), and/or a therapy mode (to begin a therapy session). The various modes of processor **144** may include waiting periods at the beginning, end, or at any time during. For example, a placement mode may include a waiting period at the end of the mode to provide a period during which a subject may fall asleep. A therapy mode may include a similar waiting period at the beginning of the mode. Additionally or alternatively, processor **144** may be configured to provide waiting periods separate from the described modes, in order to provide a desired temporal spacing between system activities. Implant unit **110**, as shown in FIG. **3**, may additionally include a plurality of field-generating implant electrodes **158***a*, **158***b*. The electrodes may include any suitable shape and/or orientation on the implant unit so long as the electrodes may be configured to generate an electric field in the body of a patient. Implant electrodes **158***a* and **158***b* may also include any suitable conductive material (e.g., copper, silver, gold, platinum, iridium, platinum-iridium, platinum-gold, conductive polymers, etc.) or combinations of conductive (and/or noble metals) materials. In some embodiments, for example, the electrodes may include short line electrodes, circular electrodes, and/or circular pairs of electrodes. As shown in FIG. **4**, electrodes **158***a* and **158***b* may be located on an end of a first extension **162***a* of an elongate arm **162**. The electrodes, however, may be located on any portion of implant unit **110**. Additionally, implant unit **110** may include electrodes **158***a*, **158***b* located at a plurality of locations, for example on an end of both a first extension **162***a* and a second extension **162***b* of elongate arm **162**, as illustrated, for example, in FIG. **5**. Implant electrodes **158***a*, **158***b* may have a thickness between about 200 nanometers and 1 millimeter. Anode and cathode electrode pairs of electrodes **158***a*, **158***b* may be spaced apart by about a distance of about 0.2 mm to 25 mm. In additional embodiments, anode and cathode electrode pairs may be spaced apart by a distance of about 1 mm to 10 mm, or between 4 mm and 7 mm. Adjacent anodes or adjacent cathodes may be spaced apart by distances as small as 0.001 mm or less, or as great as 25 mm or more. In

some embodiments, adjacent anodes or adjacent cathodes may be spaced apart by a distance between about 0.2 mm and 1 mm.

FIG. **4** provides a schematic representation of an exemplary configuration of implant unit **110**. As illustrated in FIG. **4**, in one embodiment, the field-generating electrodes **158***a* and **158***b* may include two sets of four circular electrodes, provided on flexible carrier **161**, with one set of electrodes providing an anode and the other set of electrodes providing a cathode. Implant unit **110** may include one or more structural elements to facilitate implantation of implant unit **110** into the body of a patient. Such elements may include, for example, elongated arms, suture holes, polymeric surgical mesh, biological glue, spikes of flexible carrier protruding to anchor to the tissue, spikes of additional biocompatible material for the same purpose, etc. that facilitate alignment of implant unit **110** in a desired orientation within a patient's body and provide attachment points for securing implant unit **110** within a body. For example, in some embodiments, implant unit **110** may include an elongate arm **162** having a first extension **162***a* and, optionally, a second extension **162***b*. Extensions **162***a* and **162***b* may aid in orienting implant unit **110** with respect to a particular muscle (e.g., the genioglossus muscle), a nerve within a patient's body, or a surface within a body above a nerve. For example, first and second extensions **162***a*, **162***b* may be configured to enable the implant unit to conform at least partially around soft or hard tissue (e.g., nerve, bone, or muscle, etc.) beneath a patient's skin. Further, implant unit **110** may also include one or more suture holes **160** located anywhere on flexible carrier **161**. For example, in some embodiments, suture holes **160** may be placed on second extension **162***b* of elongate arm **162** and/or on first extension **162***a* of elongate arm **162**. Implant unit **110** may be constructed in various shapes. Additionally, or alternatively, implant unit **110** may include surgical mesh **1050** or other perforatable material, described in greater detail below with respect to FIG. **10**. In some embodiments, implant unit may appear substantially as illustrated in FIG. **4**. In other embodiments, implant unit **110** may lack illustrated structures such as second extension **162***b*, or may have additional or different structures in different orientations. Additionally, implant unit **110** may be formed with a generally triangular, circular, or rectangular shape, as an alternative to the winged shape shown in FIG. **4**. In some embodiments, the shape of implant unit **110** (e.g., as shown in FIG. **4**) may facilitate orientation of implant unit **110** with respect to a particular nerve to be modulated. Thus, other regular or irregular shapes may be adopted in order to facilitate implantation in differing parts of the body.

As illustrated in FIG. **4**, secondary antenna **152** and electrodes **158***a*, **158***b* may be mounted on or integrated with flexible carrier **161**. Various circuit components and connecting wires (discussed further below) may be used to connect secondary antenna with implant electrodes **158***a* and **158***b*. To protect the antenna, electrodes, circuit components, and connecting wires from the environment within a patient's body, implant unit **110** may include a protective coating that encapsulates implant unit **110**. In some embodiments, the protective coating may be made from a flexible material to enable bending along with flexible carrier **161**. The encapsulation material of the protective coating may also resist humidity penetration and protect against corrosion. In some embodiments, the protective coating may include a plurality of layers, including different materials or combinations of materials in different layers

FIG. **5** is a perspective view of an alternate embodiment of an implant unit **110**, according to an exemplary embodiment of the present disclosure. As illustrated in FIG. **5**, implant unit **110** may include a plurality of electrodes **158***a*, **158***b* located, for example, at the ends of first extension **162***a* and second extension **162***b*. FIG. **5** illustrates an embodiment wherein implant electrodes **158***a* and **158***b* include short line electrodes. FIG. **10** is a photograph illustrating additional features of one embodiment of implant unit **110**. Exemplary embodiments may incorporate some or all of the features illustrated in FIG. **10**. A protective coating of implant unit **110** may include a primary capsule **1021**. Primary capsule **1021** may encapsulate the implant unit **110** and may provide mechanical protection for the implant unit **110**. For example, the components of implant unit **110** may be delicate, and the need to handle the implant unit **110** prior to implantation may require additional protection for the components of implant unit **110**. Primary capsule **1021** may provide such protection. Primary capsule **1021** may encapsulate all or some of the components of implant unit **110**. For example, primary capsule **1021** may encapsulate primary antenna **152**, carrier **161**, and circuit **180**, while leaving electrodes **158***a*, **158***b* exposed. In alternative embodiments, different combinations of components may be encapsulated or exposed. Primary capsule **1021** may be fashioned of a material and thickness such that implant unit **110** remains flexible after encapsulation. Primary capsule **1021** may include any suitable bio-compatible material, such as silicone, or polyimides, phenyltrimethoxysilane (PTMS), polymethyl methacrylate (PMMA), Parylene C, liquid polyimide, laminated polyimide, polyimide, Kapton, black epoxy, polyether ketone (PEEK), Liquid Crystal Polymer (LCP), or any other suitable biocompatible coating.

The protective coating of implant unit **110** may also include a secondary capsule (not shown). A secondary capsule may provide environmental protection for the implant unit **110** when it is implanted in the body. For example, primary capsule **1021**, when constructed of silicone, may be subject to moisture incursion from the body, which may limit a life-span of the implant unit **110** due to possible corrosive effects. A secondary capsule may be provided underneath the primary capsule to protect implant unit **110** from the corrosive effects of bodily implantation. For example, a layer of parylene C may serve as a secondary capsule and may be provided to encapsulate all or some of the components of implant unit **110**. The secondary capsule may, in turn, be encapsulated by primary capsule **1021**. A secondary capsule, may include, for example parylene C or any other suitable material to prevent the effects of moisture incursion on implant unit **110**. In some embodiments, a secondary capsule layer may be deposited by chemical vapor deposition and may have a thickness of about 1 molecule in thickness, between 1 and 5 molecules in thickness, or any other suitable film thickness.

Some combinations of primary and secondary capsule materials, such as silicone and parylene C, may bond relatively weakly to one another. Where such combinations of materials are used, a plurality penetrating holes **1030** may be provided to pass through both carrier **161** and a secondary capsule to improve the adherence of the primary capsule. When penetrating holes **1030** are provided, the material of primary capsule **1021** may flow through the penetrating holes, permitting the material of primary capsule **1021** to flow into and adhere to itself. A plurality of penetrating holes **1030** provided through carrier **161** and a secondary capsule may provide a multitude of anchor points to permit a primary capsule **1021** material to self adhere. Penetrating holes **1030** may be provided such that, after encapsulation by primary capsule **1021**, the holes **1030** remain, or they may be provided such that, after encapsulation, the holes **1030** are filled in.

Also illustrated in FIG. **10** is encapsulated surgical mesh **1050**. Surgical mesh **1050** may provide a larger target area for surgeons to use when suturing implant unit **110** into place during implantation. The entire surgical mesh **1050** may be encapsulated by primary capsule **1021**, permitting a surgeon to pass a needle through any portion of the mesh without compromising the integrity of implant unit **110**. Surgical mesh **1050** may additionally be used to cover suture holes **160**, permitting larger suture holes **160** that may provide surgeons with a greater target area. Surgical mesh **1050** may also encourage surrounding tissue to bond with implant unit **110**. In some embodiments, a surgeon may pass a surgical suture needle through suture holes **160**, located on one extension **162***a* of an elongate arm **162** of implant unit **110**, through tissue of the subject, and through surgical mesh **1050** provided on a second extension **162***b* of elongate arm **162** of implant unit **110**. In this embodiment, the larger target area provided by surgical mesh **1050** may facilitate the suturing process because it may be more difficult to precisely locate a suture needle after passing it through tissue. Implantantation and suturing procedures may be further facilitated through the use of a delivery tool, described in greater detail below. The capsules of implant unit **110** may be provided such that implant unit **110** remains flexible after encapsulation. Additionally, implant unit **110** may include meandering electrical traces **1060** in order to maintain electrical contact under flexural conditions. As used herein, meandering electrical traces **1060** may include any electrical trace that is longer than the shortest distance between the points that it connects. Meandering electrical traces **1060** may also include any trace of sufficient length so as to maintain electrical conductivity during flexing of a carrier on which it is located. For example, as shown in FIG. **10**, meandering electrical traces **1060** may be configured as lines having successive curves, such as waves or the like. Repeated flexing of carrier **161** on which electrical traces are deposited may cause degradation of the electrical traces, as they are repeatedly stressed with the flexure of carrier **161**. Meandering electrical traces **1060** may provide an increased lifetime, as the additional slack provided may serve to reduce stress in the traces during flexing of carrier **161**. Meandering electrical traces **1060** may include any suitable conductive material, such as gold, platinum, titanium, copper, silver, iridium, platinum-iridium, platinum-gold, conductive polymers, any conductive biocompatible material, and/or combinations of conductive (and/or noble metals) materials.

In additional embodiments consistent with the present disclosure, conductive electrical elements of implant unit **110**, such as meandering traces **1060** and electrodes **158***a*, **158***b* may be provided through a progressive metallization layering method. In some embodiments, flexible carrier **161** may include a material, such as liquid crystal polymer, that bonds relatively weakly to conductive metals desirable for use as conductive electrical elements, such as titanium and/or gold. A progressive metallization layering method may utilize a temporary bonding layer, including a metal, such as nickel, that may bond more strongly to flexible carrier **161**. The temporary bonding layer may be layered with the metals desirable for use as conductive electrical elements and used to provide an initial bond with the material of flexible carrier **161**. The temporary bonding layer may then be removed through dissolution, erosion, or similar technique, through flexible carrier **161**, leaving the desirable metals in place in flexible carrier **161**.

In one embodiment, a progressive metallization layering method may be utilized to provide gold and titanium conductive elements on a liquid crystal polymer carrier **161**. The conductive elements may be constructed from progressive layers of nickel, gold, and titanium. Next, liquid crystal polymer may be molded around the conductive elements, bonding strongly with the nickel layer and forming a recess containing the layered conductive element. Finally, the nickel may be removed through the liquid crystal polymer through dissolution, erosion, or similar technique. The removal of nickel leaves the gold/titanium layered conductive element in place, held tightly in the liquid crystal polymer recess created during the molding process.

Returning to FIGS. **2** and **3**, external unit **120** may be configured to communicate with implant unit **110**. For example, in some embodiments, a primary signal may be generated on primary antenna **150**, using, e.g., processor **144**, signal source **142**, and amplifier **146**. More specifically, in one embodiment, power source **140** may be configured to provide power to one or both of the processor **144** and the signal source **142**. The processor **144** may be configured to cause signal source **142** to generate a signal (e.g., an RF energy signal). Signal source **142** may be configured to output the generated signal to amplifier **146**, which may amplify the signal generated by signal source **142**. The amount of amplification and, therefore, the amplitude of the signal may be controlled, for example, by processor **144**. The amount of gain or amplification that processor **144** causes amplifier **146** to apply to the signal may depend on a variety of factors, including, but not limited to, the shape, size, and/or configuration of primary antenna **150**, the size of the patient, the location of implant unit **110** in the patient, the shape, size, and/or configuration of secondary antenna **152**, a degree of coupling between primary antenna **150** and secondary antenna **152** (discussed further below), a desired magnitude of electric field to be generated by implant electrodes **158***a*, **158***b*, etc. Amplifier **146** may output the amplified signal to primary antenna **150**.

External unit **120** may communicate a primary signal on primary antenna **150** to the secondary antenna **152** of implant unit **110**. This communication may result from coupling between primary antenna **150** and secondary antenna **152**. Such coupling of the primary antenna **150** and the secondary antenna **152** may include any interaction between the primary antenna **150** and the secondary antenna **152** that causes a signal on the secondary antenna **152** in response to a signal applied to the primary antenna **150**. In some embodiments, coupling between the primary and secondary antennas **150**, **152** may include capacitive coupling, inductive coupling, radiofrequency coupling, etc. and any combinations thereof.

Coupling between primary antenna **150** and secondary antenna **152** may depend on the proximity of the primary antenna **150** relative to the secondary antenna **152**. That is, in some embodiments, an efficiency or degree of coupling between primary antenna **150** and secondary antenna **152** may depend on the proximity of the primary antenna **150** to the secondary antenna **152**. The proximity of the primary and secondary antennas **150**, **152** may be expressed in terms of a coaxial offset (e.g., a distance between the primary and secondary antennas when central axes of the primary and secondary antennas are co-aligned), a lateral offset (e.g., a distance between a central axis of the primary antenna and a central axis of the secondary antenna), and/or an angular offset (e.g., an angular difference between the central axes of the primary and secondary antennas). In some embodiments, a theoretical maximum efficiency of coupling may exist between primary antenna **150** and secondary antenna **152** when both the coaxial offset, the lateral offset, and the angular offset are zero. Increasing any of the coaxial offset, the lateral offset, and the angular offset may have the effect of reducing

the efficiency or degree of coupling between primary antenna **150** and secondary antenna **152**.

As a result of coupling between primary antenna **150** and secondary antenna **152**, a secondary signal may arise on secondary antenna **152** when the primary signal is present on the primary antenna **150**. Such coupling may include inductive/magnetic coupling, RF coupling/transmission, capacitive coupling, or any other mechanism where a secondary signal may be generated on secondary antenna **152** in response to a primary signal generated on primary antenna **150**. Coupling may refer to any interaction between the primary and secondary antennas. In addition to the coupling between primary antenna **150** and secondary antenna **152**, circuit components associated with implant unit **110** may also affect the secondary signal on secondary antenna **152**. Thus, the secondary signal on secondary antenna **152** may refer to any and all signals and signal components present on secondary antenna **152** regardless of the source.

While the presence of a primary signal on primary antenna **150** may cause or induce a secondary signal on secondary antenna **152**, the coupling between the two antennas may also lead to a coupled signal or signal components on the primary antenna **150** as a result of the secondary signal present on secondary antenna **152**. A signal on primary antenna **150** induced by a secondary signal on secondary antenna **152** may be referred to as a primary coupled signal component. The primary signal may refer to any and all signals or signal components present on primary antenna **150**, regardless of source, and the primary coupled signal component may refer to any signal or signal component arising on the primary antenna **150** as a result of coupling with signals present on secondary antenna **152**. Thus, in some embodiments, the primary coupled signal component may contribute to the primary signal on primary antenna **150**.

Implant unit **110** may be configured to respond to external unit **120**. For example, in some embodiments, a primary signal generated on primary coil **150** may cause a secondary signal on secondary antenna **152**, which in turn, may cause one or more responses by implant unit **110**. In some embodiments, the response of implant unit **110** may include the generation of an electric field between implant electrodes **158***a* and **158***b*.

FIG. **6** illustrates circuitry **170** that may be included in external unit **120** and circuitry **180** that may be included in implant unit **110**. Additional, different, or fewer circuit components may be included in either or both of circuitry **170** and circuitry **180**. As shown in FIG. **6**, secondary antenna **152** may be arranged in electrical communication with implant electrodes **158***a*, **158***b*. In some embodiments, circuitry connecting secondary antenna **152** with implant electrodes **158***a* and **158***b* may cause a voltage potential across implant electrodes **158***a* and **158***b* in the presence of a secondary signal on secondary antenna **152**. This voltage potential may be referred to as a field inducing signal, as this voltage potential may generate an electric field between implant electrodes **158***a* and **158***b*. More broadly, the field inducing signal may include any signal (e.g., voltage potential) applied to electrodes associated with the implant unit that may result in an electric field being generated between the electrodes.

Energy transfer between primary antenna **150** and secondary antenna **152** via the primary signal may be improved when a resonant frequency of primary antenna **150** and its associated circuitry **170** matches that of secondary antenna **152** and its associated circuitry **180**. As used herein a resonant frequency match between two antennas may be characterized by the proximity of two resonant frequencies to one another. For example, a resonant frequency match may be considered to occur when two resonant frequencies are within 30%, 20%, 10%, 5%, 3%, 1%, 0.5%, 0.1%, or less of each other. Accordingly, a resonant frequency mismatch may be considered to occur when two resonant frequencies do not match. The proximity of the two resonant frequencies required to be considered a match may depend on the circumstances of energy transfer between the two antennas. A resonant frequency match between two antennas may also be characterized by the efficiency of energy transfer between the antennas. The efficiency of energy transfer between two antennas may depend on several factors, one of which may be the degree to which the resonant frequencies of the antennas match. Thus, if all other factors are held constant, changing the resonant frequency of one antenna with respect to the other will alter the efficiency of energy transfer. A resonant frequency match between two antennas may be considered to occur when the efficiency of energy transfer is within 50% or greater of a maximum energy transfer when all other factors remain constant. In some embodiments, a resonant frequency match may require energy transfer efficiencies of 60%, 70%, 80%, 90%, 95% or greater.

Several embodiments are provided in order to appropriately match resonant frequencies between a primary signal and a secondary antenna **152**. Because the secondary antenna **152** is intended for implantation with implant unit **110**, it may be difficult to adjust the resonant frequency of the antenna during use. Furthermore, due to the possibility of moisture incursion into primary capsule **1201** encapsulating implant unit **110**, implant circuitry **180**, and secondary antenna **152**, a resonant frequency of the implant unit **110** may drift after implantation. Other factors present during implantation may also influence the frequency drift of implant unit **110** after implantation. This drifting of the resonant frequency may last for several days to several months after implantation before stabilizing. For example, the resonant frequency of an implant unit **110** may drift from 8.1 kHz to 7.9 kHz. Through experimentation or simulation, it may be possible to predict by how much the resonant frequency may drift. Thus, using the example above, if a long term resonant frequency value of 7.9 kHz is desired, an implant unit **110** may be manufactured with a resonant frequency value of 8.1 kHz prior to implantation.

Resonant frequency values of manufactured implant units **110** may be adjusted during the manufacturing process through the use of at least one trimming capacitor. In one embodiment, carrier **161** may be manufactured with all or some of the components of the final implant unit, including, for example, secondary antenna **152**, implant circuitry **180**, modulation electrodes **158***a*, **158***b*. The resonant frequency of this assembly may then be measured or otherwise determined. Due to variations in manufacturing processes and materials, the resonant frequency of each manufactured unit may differ. Thus, in order to meet a specific resonance frequency, each implant unit may be adjusted through the addition of one or more trimming capacitors to the implant circuitry **180** prior to encapsulation. In one embodiment, a capacitor may be laser trimmed to an exact capacitance value before insertion into implant circuitry **180**. In another embodiment, a stock capacitor of known value may be inserted into implant circuitry **180**. In still another embodiment, a plurality of capacitors may be inserted into implanted circuitry **180** to appropriately adjust the resonant frequency of implant unit **110**. Such a plurality of capacitors may include a series of capacitors having progressively smaller capacitance values, and a resonant frequency of the assembly may be measured after the insertion of each capacitor prior to choosing and inserting the next. In this fashion, implantable

circuit **180** may include at least one capacitor configured to create a predetermined mismatch between a resonant frequency of implantable circuit **180** and external circuit **170**.

In addition to resonant frequency drift in implant unit **110**, a resonant frequency of primary antenna **152** may be altered due to the application of the antenna **152** to the skin of a subject. That is, when primary antenna **152** is bent to conform to the skin of a subject, the spatial relationship coils within primary antenna **152** may shift, causing a change in resonant frequency. In order to address this, a processor **144** of the external unit may be configured to determine a resonant frequency mismatch between primary antenna **152** and secondary antenna **150**, and adjust a resonant frequency of primary antenna **152** in order to reduce or eliminate the resonant frequency mismatch. During transmission of a primary signal from primary antenna **150** to secondary antenna **152**, processor **144** may be configured to determine a resonant frequency mismatch based on a primary coupled signal component present on the primary antenna **150** due to coupling between primary antenna **152** and secondary antenna **150**. Monitoring a primary coupled signal component by the processor **144** may provide an indication of transmission efficiency, which may in turn be an indication of resonant frequency mismatch. The primary coupled signal component and the interaction between primary antenna **152** and secondary antenna **150** are explained in greater detail below.

Upon determining a resonant frequency mismatch between a primary antenna **150** and a secondary antenna **152**, processor **144** may adjust the resonant frequency of a self-resonant transmitter circuit including the primary antenna to reduce the mismatch. A self-resonant transmitter circuit may include features to permit adjustment of a resonant frequency of the circuit. Such adjustment may be performed, for example through the selective inclusion and exclusion of at least one capacitor into or out of a self-resonant transmitter circuit. Adding (or subtracting) capacitors to the self-resonant transmitter circuit may cause a change in the resonant frequency of the circuit. In the currently described embodiment, the self-resonant transmitter circuit may be provided with one or more trim capacitors configured, through processor **144** controlled switches, for selective inclusion and exclusion. The switches may include, for example, transistors or relays. Thus, processor **144** may include or exclude a capacitor from the self-resonant transmitter circuit by opening or closing a switch associated with the respective capacitor. Providing a single capacitor, therefore, permits processor **144** to switch the resonant frequency of the self-resonant transmitter circuit between two different values. In an exemplary embodiment, a bank of six capacitors may be provided, permitting processor **144** to switch the resonant frequency of the self-resonant transmitter circuit between 64 (i.e., 2^6) different values. In alternative embodiments, more or fewer capacitors may be provided for adjusting the resonant frequency of the self-resonant transmitter circuit.

In an exemplary embodiment, processor **144** may be configured to switch capacitors from a capacitor bank into and out of the self-resonant transmitter circuit during transmission of a primary signal to determine a capacitor combination that changes (e.g., increases) transmission efficiency and resonant frequency match. In some embodiments, processor **144** may be configured to select an optimal combination of capacitors to provide a best resonant frequency match. In alternative embodiments, processor **144** may be configured to select a combination of capacitors that provides a resonant frequency match surpassing a predetermined threshold, regardless of whether such combination produces an optimal resonant frequency match.

Resonant frequency matching between primary antenna **150** and secondary antenna **152** may increase the efficiency of energy transfer between the antennas. In further embodiments processor **144** may be configured to adjust the operation of elements within external unit **120** to match a frequency of a primary signal with a resonant frequency of primary antenna **150**.

FIG. **13** depicts an additional embodiment illustrating a self-resonant transmitter circuit employing a modified class D amplifier for use with resonant frequency matching methods. Modified class D amplifier **1600** may be used in place of, or in addition to, any or all of the elements of external unit **120** depicted in FIG. **3**. For example, modified class D amplifier **1600** may replace signal source **142** and amplifier **146**. In this embodiment, processor **144** may be configured to adjust the operation of a class D amplifier to provide a frequency match between a generated signal and a resonant frequency of a primary antenna **150**. Because the resonant frequency of primary antenna **150** may be adjusted to match that of secondary antenna **152** during operation, it may be beneficial to adjust the frequency of the generated signal as well to improve efficiency within the self-resonant transmitter circuit of an external unit **120**. Modified class D amplifier **1600** may be used to provide such an adjustment as follows. Modified class D amplifier **1600** includes an H bridge **1601** including switches (such as MOSFETs) **1620**. Between the switches is self-resonant transmitter circuit **1610**. Power to the modified class D amplifier is supplied by supply voltage **1650**, which may be supplied from a battery, for example. As shown in FIG. **13**, self-resonant transmitter circuit **1610** may include multiple capacitances **1640** and inductances **1660**. Capacitances **1640** may include multiple capacitors, combinations of which may be chosen from among trim capacitors as described above, in order to selectively provide an appropriate value of capacitance **1640**. The value of capacitance **1640** may be selected for resonant frequency matching to secondary antenna **152**. Inductances **1660** may be provided at least partially by primary antenna **150**. Processor **144** may also adjust a driving frequency of the H bridge switches **1620** in order to generate a signal of a frequency that matches the resonant frequency of self-resonant circuit **1610**. By selectively opening and closing switches **1620** appropriately, the DC signal of supply voltage **1650** may be converted into a square wave of a selected frequency. This frequency may be selected to match the resonant frequency of self-resonant circuit **1610** in order to increase the efficiency of the circuit.

FIG. **14** depicts an additional embodiment illustrating a pulsed mode self-resonant transmitter **1700** for use with resonant frequency matching methods. Pulsed mode self-resonant transmitter **1700** may be used in place of, or in addition to, any or all of the elements of external unit **120** depicted in FIG. **3**. For example, pulsed mode self-resonant transmitter **1700** may replace signal source **142** and amplifier **146**. In this embodiment, processor **144** may be configured to control the circuit through a power switching unit, depicted in the present embodiment as switch **1730**. A power switching unit may include a transistor, relay, or similar switching device. Pulsed mode self-resonant transmitter **1700** may include a primary power source **1780**, for example, a battery or alternative source of power. Transmitter **1700** may include a power storage unit, such as storage capacitor **1750**. Other suitable power storage units may also be utilized, such as an inductor and/or battery, as well as combinations of these storage elements. Transmitter **1700** may also include a self-resonant transmitter circuit **1710**, including resonance capacitance **1720** and a resonance inductance **1760**. Resonance inductance **1760** may be provided at least partially by primary antenna **150**.

Transmitter **1700** may operate in the following manner, among others. For example, processor **144** may control the operation of switch **1730**. When switch **1730** is maintained in an open position, current from power source **1780** may flow into storage capacitor **1750**, which may thereby accumulate an electrical charge. When switch **1730** is closed, charged storage capacitor **1750** may drive current into the self-resonant circuit **1710** during a current loading period, where energy may be stored in inductance **1760**. Due to the operation of diode **1770**, current flow into circuit **1710** may be cut off after a period of energy accumulation. The current transferred to circuit **1710** may then oscillate freely within circuit **1710** at the resonant frequency of circuit **1710**, and thus generate a signal for transmission to the implant through primary antenna **150** (which is included in the circuit and creates at least a portion of inductance **1760**). Because the signal is generated by the self resonance of circuit **1710**, it will match the resonant frequency of circuit **1710** and a more efficient transmission may be created.

Components of transmitter **1700** may be chosen such that the current loading period may be approximately two microseconds and a period of free oscillation in circuit **1710** may be between 10 and 20 microseconds. Other components may be selected, however, to provide any desired current loading period or free oscillation period. As described elsewhere in this disclosure, stimulation pulses of varying lengths may be desired. Stimulation pulses of longer than a single period of free oscillation may be constructed by multiple cycles of loading and releasing energy from storage capacitor **1750** into circuit **1710**. Storage capacitor **1750** may itself be chosen to store enough charge to drive a large number of oscillation cycles (e.g. between 10 and 100) in order to construct entire stimulation pulses without requiring recharging from power source **1780**.

Pulsed mode self-resonant transmitter **1700** may provide several advantages. As described above, because the transmission signal is generated by the self-resonance of circuit **1710**, it likely will match the resonant frequency of circuit **1710**, obviating a need to match the frequency of the generated signal with the circuit resonance frequency. Further, because energy is stored in capacitor **1750** prior to discharge into circuit **1710**, a greater flexibility in choice of power source **1780** may be provided. Effective neural stimulation may depend on current levels that rise rapidly. To achieve this with a battery alone may require a high-voltage and/or high-current battery. This need may be obviated by transmitter **1700**, which permits the delivery of a very high peak current through the use of a relatively low voltage/low current battery. Transmitter **1700** may use fewer switches (e.g. transistors) than does a conventional amplifying circuit. Each switch may be a source of energy loss, contributing to an overall less efficient circuit. The presence of a single switch **1730** in transmitter **1700** may increase the efficiency of the circuit as a whole.

The field inducing signal may be generated as a result of conditioning of the secondary signal by circuitry **180**. As shown in FIG. **6**, circuitry **170** of external unit **120** may be configured to generate an AC primary signal on primary antenna **150** that may cause an AC secondary signal on secondary antenna **152**. In certain embodiments, however, it may be advantageous (e.g., in order to generate a unidirectional electric field for modulation of a nerve) to provide a DC field inducing signal at implant electrodes **158***a* and **158***b*. To convert the AC secondary signal on secondary antenna **152** to a DC field inducing signal, circuitry **180** in implant unit **110** may include an AC-DC converter. The AC to DC converter may include any suitable converter known to those skilled in the art. For example, in some embodiments the AC-DC converter may include rectification circuit components including, for example, diode **156** and appropriate capacitors and resistors. In alternative embodiments, implant unit **110** may include an AC-AC converter, or no converter, in order to provide an AC field inducing signal at implant electrodes **158***a* and **158***b*.

As noted above, the field inducing signal may be configured to generate an electric field between implant electrodes **158***a* and **158***b*. In some instances, the magnitude and/or duration of the generated electric field resulting from the field inducing signal may be sufficient to modulate one or more nerves in the vicinity of electrodes **158***a* and **158***b*. In such cases, the field inducing signal may be referred to as a modulation signal. In other instances, the magnitude and/or duration of the field inducing signal may generate an electric field that does not result in nerve modulation. In such cases, the field inducing signal may be referred to as a sub-modulation signal.

Various types of field inducing signals may constitute modulation signals. For example, in some embodiments, a modulation signal may include a moderate amplitude and moderate duration, while in other embodiments, a modulation signal may include a higher amplitude and a shorter duration. Various amplitudes and/or durations of field-inducing signals across electrodes **158***a*, **158***b* may result in modulation signals, and whether a field-inducing signal rises to the level of a modulation signal can depend on many factors (e.g., distance from a particular nerve to be stimulated; whether the nerve is branched; orientation of the induced electric field with respect to the nerve; type of tissue present between the electrodes and the nerve; etc.).

Whether a field inducing signal constitutes a modulation signal (resulting in an electric field that may cause nerve modulation) or a sub-modulation signal (resulting in an electric field not intended to cause nerve modulation) may ultimately be controlled by processor **144** of external unit **120**. For example, in certain situations, processor **144** may determine that nerve modulation is appropriate. Under these conditions, processor **144** may cause signal source **144** and amplifier **146** to generate a modulation control signal on primary antenna **150** (i.e., a signal having a magnitude and/or duration selected such that a resulting secondary signal on secondary antenna **152** will provide a modulation signal at implant electrodes **158***a* and **158***b*).

Processor **144** may be configured to limit an amount of energy transferred from external unit **120** to implant unit **110**. For example, in some embodiments, implant unit **110** may be associated with a threshold energy limit that may take into account multiple factors associated with the patient and/or the implant. For example, in some cases, certain nerves of a patient should receive no more than a predetermined maximum amount of energy to minimize the risk of damaging the nerves and/or surrounding tissue. Additionally, circuitry **180** of implant unit **110** may include components having a maximum operating voltage or power level that may contribute to a practical threshold energy limit of implant unit **110**. Processor **144** may be configured to account for such limitations when setting the magnitude and/or duration of a primary signal to be applied to primary antenna **150**.

In addition to determining an upper limit of power that may be delivered to implant unit **110**, processor **144** may also determine a lower power threshold based, at least in part, on an efficacy of the delivered power. The lower power threshold may be computed based on a minimum amount of power that enables nerve modulation (e.g., signals having power levels above the lower power threshold may constitute modulation

signals while signals having power levels below the lower power threshold may constitute sub-modulation signals).

A lower power threshold may also be measured or provided in alternative ways. For example, appropriate circuitry or sensors in the implant unit **110** may measure a lower power threshold. A lower power threshold may be computed or sensed by an additional external device, and subsequently programmed into processor **144**, or programmed into implant unit **110**. Alternatively, implant unit **110** may be constructed with circuitry **180** specifically chosen to generate signals at the electrodes of at least the lower power threshold. In still another embodiment, an antenna of external unit **120** may be adjusted to accommodate or produce a signal corresponding to a specific lower power threshold. The lower power threshold may vary from patient to patient, and may take into account multiple factors, such as, for example, modulation characteristics of a particular patient's nerve fibers, a distance between implant unit **110** and external unit **120** after implantation, and the size and configuration of implant unit components (e.g., antenna and implant electrodes), etc.

Processor **144** may also be configured to cause application of sub-modulation control signals to primary antenna **150**. Such sub-modulation control signals may include an amplitude and/or duration that result in a sub-modulation signal at electrodes **158***a*, **158***b*. While such sub-modulation control signals may not result in nerve modulation, such sub-modulation control signals may enable feedback-based control of the nerve modulation system. That is, in some embodiments, processor **144** may be configured to cause application of a sub-modulation control signal to primary antenna **150**. This signal may induce a secondary signal on secondary antenna **152**, which, in turn, may induce a primary coupled signal component on primary antenna **150**.

To analyze the primary coupled signal component induced on primary antenna **150**, external unit **120** may include feedback circuit **148** (e.g., a signal analyzer or detector, etc.), which may be placed in direct or indirect communication with primary antenna **150** and processor **144**. Sub-modulation control signals may be applied to primary antenna **150** at any desired periodicity. In some embodiments, the sub-modulation control signals may be applied to primary antenna **150** at a rate of one every five seconds (or longer). In other embodiments, the sub-modulation control signals may be applied more frequently (e.g., once every two seconds, once per second, once per millisecond, once per nanosecond, or multiple times per second). Further, it should be noted that feedback may also be received upon application of modulation control signals to primary antenna **150** (i.e., those that result in nerve modulation), as such modulation control signals may also result in generation of a primary coupled signal component on primary antenna **150**.

The primary coupled signal component may be fed to processor **144** by feedback circuit **148** and may be used as a basis for determining a degree of coupling between primary antenna **150** and secondary antenna **152**. The degree of coupling may enable determination of the efficacy of the energy transfer between two antennas. Processor **144** may also use the determined degree of coupling in regulating delivery of power to implant unit **110**.

Processor **144** may be configured with any suitable logic for determining how to regulate power transfer to implant unit **110** based on the determined degree of coupling. For example, where the primary coupled signal component indicates that a degree of coupling has changed from a baseline coupling level, processor **144** may determine that secondary antenna **152** has moved with respect to primary antenna **150** (either in coaxial offset, lateral offset, or angular offset, or any combination). Such movement, for example, may be associated with a movement of the implant unit **110**, and the tissue that it is associated with based on its implant location. Thus, in such situations, processor **144** may determine that modulation of a nerve in the patient's body is appropriate. More particularly, in response to an indication of a change in coupling, processor **144**, in some embodiments, may cause application of a modulation control signal to primary antenna **150** in order to generate a modulation signal at implant electrodes **158***a*, **158***b*, e.g., to cause modulation of a nerve of the patient.

In an embodiment for the treatment of OSA, movement of an implant unit **110** may be associated with movement of the tongue, which may indicate the onset of a sleep apnea event or a sleep apnea precursor. The onset of a sleep apnea event or sleep apnea precursor may require the stimulation of the genioglossus muscle of the patient to relieve or avert the event. Such stimulation may result in contraction of the muscle and movement of the patient's tongue away from the patient's airway.

In embodiments for the treatment of head pain, including migraines, processor **144** may be configured to generate a modulation control signal based on a signal from a user, for example, or a detected level of neural activity in a sensory neuron (e.g. the greater occipital nerve or trigeminal nerve) associated with head pain. A modulation control signal generated by the processor and applied to the primary antenna **150** may generate a modulation signal at implant electrodes **158***a*, **158***b*, e.g., to cause inhibition or blocking of a sensory nerve of the patient. Such inhibition or blocking may decrease or eliminate the sensation of pain for the patient.

In embodiments for the treatment of hypertension, processor **144** may be configured to generate a modulation control signal based on, for example, pre-programmed instructions and/or signals from an implant indicative of blood pressure. A modulation control signal generated by the processor and applied to the primary antenna **150** may generate a modulation signal at implant electrodes **158***a*, **158***b*, e.g., to cause either inhibition or stimulation of nerve of a patient, depending on the requirements. For example, a neuromodulator placed in a carotid artery or jugular artery (i.e. in the vicinity of a carotid baroreceptor), may receive a modulation control signal tailored to induce a stimulation signal at the electrodes, thereby causing the glossopharyngeal nerve associated with the carotid baroreceptors to fire at an increased rate in order to signal the brain to lower blood pressure. Similar modulation of the glossopharyngeal nerve may be achieved with a neuromodulator implanted in a subcutaneous location in a patient's neck or behind a patient's ear. A neuromodulator place in a renal artery may receive a modulation control signal tailored to cause an inhibiting or blocking signal at the electrodes, thereby inhibiting a signal to raise blood pressure carried from the renal nerves to the kidneys.

Modulation control signals may include stimulation control signals, and sub-modulation control signals may include sub-stimulation control signals. Stimulation control signals may have any amplitude, pulse duration, or frequency combination that results in a stimulation signal at electrodes **158***a*, **158***b*. In some embodiments (e.g., at a frequency of between about 6.5-13.6 MHz), stimulation control signals may include a pulse duration of greater than about 50 microseconds and/or an amplitude of approximately 0.5 amps, or between 0.1 amps and 1 amp, or between 0.05 amps and 3 amps. Sub-stimulation control signals may have a pulse duration less than about 500, or less than about 200 nanoseconds and/or an amplitude less than about 1 amp, 0.5 amps, 0.1 amps, 0.05 amps, or 0.01 amps. Of course, these values are meant to provide a general reference only, as various combi-

nations of values higher than or lower than the exemplary guidelines provided may or may not result in nerve stimulation.

In some embodiments, stimulation control signals may include a pulse train, wherein each pulse includes a plurality of sub-pulses. An alternating current signal (e.g., at a frequency of between about 6.5-13.6 MHz) may be used to generate the pulse train, as follows. A sub-pulse may have a duration of between 50-250 microseconds, or a duration of between 1 microsecond and 2 milliseconds, during which an alternating current signal is turned on. For example, a 200 microsecond sub-pulse of a 10 MHz alternating current signal will include approximately 2000 periods. Each pulse may, in turn, have a duration of between 100 and 500 milliseconds, during which sub-pulses occur at a frequency of between 25 and 100 Hz. For example, a 200 millisecond pulse of 50 Hz sub-pulses will include approximately 10 sub-pulses. Finally, in a pulse train, each pulse may be separated from the next by a duration of between 0.2 and 2 seconds. For example, in a pulse train of 200 millisecond pulses, each separated by 1.3 seconds from the next, a new pulse will occur every 1.5 seconds. A pulse train of this embodiment may be utilized, for example, to provide ongoing stimulation during a treatment session. In the context of OSA, a treatment session may be a period of time during which a subject is asleep and in need of treatment to prevent OSA. Such a treatment session may last anywhere from about three to ten hours. In the context of other conditions to which neural modulators of the present disclosure are applied, a treatment session may be of varying length according to the duration of the treated condition.

Processor **144** may be configured to determine a degree of coupling between primary antenna **150** and secondary antenna **152** by monitoring one or more aspects of the primary coupled signal component received through feedback circuit **148**. In some embodiments, processor **144** may determine a degree of coupling between primary antenna **150** and secondary antenna **152** by monitoring a voltage level associated with the primary coupled signal component, a current level, or any other attribute that may depend on the degree of coupling between primary antenna **150** and secondary antenna **152**. For example, in response to periodic sub-modulation signals applied to primary antenna **150**, processor **144** may determine a baseline voltage level or current level associated with the primary coupled signal component. This baseline voltage level, for example, may be associated with a range of movement of the patient's tongue when a sleep apnea event or its precursor is not occurring, e.g. during normal breathing. As the patient's tongue moves toward a position associated with a sleep apnea event or its precursor, the coaxial, lateral, or angular offset between primary antenna **150** and secondary antenna **152** may change. As a result, the degree of coupling between primary antenna **150** and secondary antenna **152** may change, and the voltage level or current level of the primary coupled signal component on primary antenna **150** may also change. Processor **144** may be configured to recognize a sleep apnea event or its precursor when a voltage level, current level, or other electrical characteristic associated with the primary coupled signal component changes by a predetermined amount or reaches a predetermined absolute value.

FIG. **7** provides a graph that illustrates this principle in more detail. For a two-coil system where one coil receives a radio frequency (RF) drive signal, graph **200** plots a rate of change in induced current in the receiving coil as a function of coaxial distance between the coils. For various coil diameters and initial displacements, graph **200** illustrates the sensitivity of the induced current to further displacement between the coils, moving them either closer together or further apart. It also indicates that, overall, the induced current in the secondary coil will decrease as the secondary coil is moved away from the primary, drive coil, i.e. the rate of change of induced current, in mA/mm, is consistently negative. The sensitivity of the induced current to further displacement between the coils may vary with distance. For example, at a separation distance of 10 mm, the rate of change in current as a function of additional displacement in a 14 mm coil is approximately −6 mA/mm. If the displacement of the coils is approximately 22 mm, the rate of change in the induced current in response to additional displacement is approximately −11 mA/mm, which corresponds to a local maximum in the rate of change of the induced current. Increasing the separation distance beyond 22 mm continues to result in a decline in the induced current in the secondary coil, but the rate of change decreases. For example, at a separation distance of about 30 mm, the 14 mm coil experiences a rate of change in the induced current in response to additional displacement of about −8 mA/mm. With this type of information, processor **144** may be able to determine a particular degree of coupling between primary antenna **150** and secondary antenna **152**, at any given time, by observing the magnitude and/or rate of change in the magnitude of the current associated with the primary coupled signal component on primary antenna **150**.

Processor **144** may be configured to determine a degree of coupling between primary antenna **150** and secondary antenna **152** by monitoring other aspects of the primary coupled signal component. For example, in some embodiments, the non-linear behavior of circuitry **180** in implant unit **110** may be monitored to determine a degree of coupling. For example, the presence, absence, magnitude, reduction and/or onset of harmonic components in the primary coupled signal component on primary antenna **150** may reflect the behavior of circuitry **180** in response to various control signals (either sub-modulation or modulation control signals) and, therefore, may be used to determine a degree of coupling between primary antenna **150** and secondary antenna **152**.

As shown in FIG. **6**, circuitry **180** in implant unit **110** may constitute a non-linear circuit due, for example, to the presence of non-linear circuit components, such as diode **156**. Such non-linear circuit components may induce non-linear voltage responses under certain operation conditions. Non-linear operation conditions may be induced when the voltage potential across diode **156** exceeds the activation threshold for diode **156**. Thus, when implant circuitry **180** is excited at a particular frequency, this circuit may oscillate at multiple frequencies. Spectrum analysis of the secondary signal on secondary antenna **152**, therefore, may reveal one or more oscillations, called harmonics, that appear at certain multiples of the excitation frequency. Through coupling of primary antenna **150** and secondary antenna **152**, any harmonics produced by implant circuitry **180** and appearing on secondary antenna **152** may also appear in the primary coupled signal component present on primary antenna **150**.

In certain embodiments, circuitry **180** may include additional circuit components that alter the characteristics of the harmonics generated in circuitry **180** above a certain transition point. Monitoring how these non-linear harmonics behave above and below the transition point may enable a determination of a degree of coupling between primary antenna **150** and secondary antenna **152**. For example, as shown in FIG. **6**, circuitry **180** may include a harmonics modifier circuit **154**, which may include any electrical components that non-linearly alter the harmonics generated in circuitry **180**. In some embodiments, harmonics modifier circuit **154** may include a pair of Zener diodes. Below a certain voltage level, these Zener diodes remain forward biased such

that no current will flow through either diode. Above the breakdown voltage of the Zener diodes, however, these devices become conductive in the reversed biased direction and will allow current to flow through harmonics modifier circuit **154**. Once the Zener diodes become conductive, they begin to affect the oscillatory behavior of circuitry **180**, and, as a result, certain harmonic oscillation frequencies may be affected (e.g., reduced in magnitude).

FIGS. **8** and **9** illustrate this effect. For example, FIG. **8** illustrates a graph **300***a* that shows the oscillatory behavior of circuitry **180** at several amplitudes ranging from about 10 nanoamps to about 20 microamps. As shown, the primary excitation frequency occurs at about 6.7 MHz and harmonics appear both at even and odd multiples of the primary excitation frequency. For example, even multiples appear at twice the excitation frequency (peak **302***a*), four times the excitation frequency (peak **304***a*) and six times the excitation frequency (peak **306***a*). As the amplitude of the excitation signal rises between 10 nanoamps and 40 microamps, the amplitude of peaks **302***a*, **304***a*, and **306***a* all increase.

FIG. **9** illustrates the effect on the even harmonic response of circuitry **180** caused by harmonics modifier circuit **154**. FIG. **9** illustrates a graph **300***b* that shows the oscillatory behavior of circuitry **180** at several amplitudes ranging from about 30 microamps to about 100 microamps. As in FIG. **8**, FIG. **9** shows a primary excitation frequency at about 6.7 MHz and second, fourth, and sixth order harmonics (peaks **302***b*, **304***b*, and **306***b*, respectively) appearing at even multiples of the excitation frequency. As the amplitude of the excitation signal rises, however, between about 30 microamps to about 100 microamps, the amplitudes of peaks **302***b*, **304***b*, and **306***b* do not continuously increase. Rather, the amplitude of the second order harmonics decreases rapidly above a certain transition level (e.g., about 80 microamps in FIG. **8**). This transition level corresponds to the level at which the Zener diodes become conductive in the reverse biased direction and begin to affect the oscillatory behavior of circuitry **180**.

Monitoring the level at which this transition occurs may enable a determination of a degree of coupling between primary antenna **150** and secondary antenna **152**. For example, in some embodiments, a patient may attach external unit **120** over an area of the skin under which implant unit **110** resides. Processor **144** can proceed to cause a series of sub-modulation control signals to be applied to primary antenna **150**, which in turn cause secondary signals on secondary antenna **152**. These sub-modulation control signals may progress over a sweep or scan of various signal amplitude levels. By monitoring the resulting primary coupled signal component on primary antenna **150** (generated through coupling with the secondary signal on secondary antenna **152**), processor **144** can determine the amplitude of primary signal (whether a sub-modulation control signal or other signal) that results in a secondary signal of sufficient magnitude to activate harmonics modifier circuit **154**. That is, processor **144** can monitor the amplitude of the second, fourth, or sixth order harmonics and determine the amplitude of the primary signal at which the amplitude of any of the even harmonics drops. FIGS. **8** and **9** illustrate the principles of detecting coupling through the measurement of non-linear harmonics. These Figures illustrate data based around a 6.7 MHz excitation frequency. These principles, however, are not limited to the 6.7 MHz excitation frequency illustrated, and may be used with a primary signal of any suitable frequency.

In some embodiments, the determined amplitude of the primary signal corresponding to the transition level of the Zener diodes (which may be referred to as a primary signal transition amplitude) may establish a baseline range when the patient attaches external unit **120** to the skin. Presumably, while the patient is awake, the tongue is not blocking the patient's airway and moves with the patients breathing in a natural range, where coupling between primary antenna **150** and secondary antenna **152** may be within a baseline range. A baseline coupling range may encompass a maximum coupling between primary antenna **150** and secondary antenna **152**. A baseline coupling range may also encompass a range that does not include a maximum coupling level between primary antenna **150** and secondary antenna **152**. Thus, the initially determined primary signal transition amplitude may be fairly representative of a non-sleep apnea condition and may be used by processor **144** as a baseline in determining a degree of coupling between primary antenna **150** and secondary antenna **152**. Optionally, processor **144** may also be configured to monitor the primary signal transition amplitude over a series of scans and select the minimum value as a baseline, as the minimum value may correspond to a condition of maximum coupling between primary antenna **150** and secondary antenna **152** during normal breathing conditions.

As the patient wears external unit **120**, processor **144** may periodically scan over a range of primary signal amplitudes to determine a current value of the primary signal transition amplitude. In some embodiments, the range of amplitudes that processor **144** selects for the scan may be based on (e.g., near) the level of the baseline primary signal transition amplitude. If a periodic scan results in determination of a primary signal transition amplitude different from the baseline primary signal transition amplitude, processor **144** may determine that there has been a change from the baseline initial conditions. For example, in some embodiments, an increase in the primary signal transition amplitude over the baseline value may indicate that there has been a reduction in the degree of coupling between primary antenna **150** and secondary antenna **152** (e.g., because the implant has moved or an internal state of the implant has changed).

In addition to determining whether a change in the degree of coupling has occurred, processor **144** may also be configured to determine a specific degree of coupling based on an observed primary signal transition amplitude. For example, in some embodiments, processor **144** may have access to a lookup table or a memory storing data that correlates various primary signal transition amplitudes with distances (or any other quantity indicative of a degree of coupling) between primary antenna **150** and secondary antenna **152**. In other embodiments, processor **144** may be configured to calculate a degree of coupling based on performance characteristics of known circuit components.

By periodically determining a degree of coupling value, processor **144** may be configured to determine, in situ, appropriate parameter values for the modulation control signal that will ultimately result in nerve modulation. For example, by determining the degree of coupling between primary antenna **150** and secondary antenna **152**, processor **144** may be configured to select characteristics of the modulation control signal (e.g., amplitude, pulse duration, frequency, etc.) that may provide a modulation signal at electrodes **158***a*, **158***b* in proportion to or otherwise related to the determined degree of coupling. In some embodiments, processor **144** may access a lookup table or other data stored in a memory correlating modulation control signal parameter values with degree of coupling. In this way, processor **144** may adjust the applied modulation control signal in response to an observed degree of coupling.

Additionally or alternatively, processor **144** may be configured to determine the degree of coupling between primary

antenna **150** and secondary antenna **152** during modulation. The tongue, or other structure on or near which the implant is located, and thus implant unit **110**, may move as a result of modulation. Thus, the degree of coupling may change during modulation. Processor **144** may be configured to determine the degree of coupling as it changes during modulation, in order to dynamically adjust characteristics of the modulation control signal according to the changing degree of coupling. This adjustment may permit processor **144** to cause implant unit **110** to provide an appropriate modulation signal at electrodes **158***a*, **158***b* throughout a modulation event. For example, processor **144** may alter the primary signal in accordance with the changing degree of coupling in order to maintain a constant modulation signal, or to cause the modulation signal to be reduced in a controlled manner according to patient needs.

More particularly, the response of processor **144** may be correlated to the determined degree of coupling. In situations where processor **144** determines that the degree of coupling between primary antenna **150** and secondary antenna has fallen only slightly below a predetermined coupling threshold (e.g, during snoring or during a small vibration of the tongue or other sleep apnea event precursor), processor **144** may determine that only a small response is necessary. Thus, processor **144** may select modulation control signal parameters that will result in a relatively small response (e.g., a short stimulation of a nerve, small muscle contraction, etc.). Where, however, processor **144** determines that the degree of coupling has fallen substantially below the predetermined coupling threshold (e.g., where the tongue has moved enough to cause a sleep apnea event), processor **144** may determine that a larger response is required. As a result, processor **144** may select modulation control signal parameters that will result in a larger response. In some embodiments, only enough power may be transmitted to implant unit **110** to cause the desired level of response. In other words, processor **144** may be configured to cause a metered response based on the determined degree of coupling between primary antenna **150** and secondary antenna **152**. As the determined degree of coupling decreases, processor **144** may cause transfer of power in increasing amounts. Such an approach may preserve battery life in the external unit **120**, may protect circuitry **170** and circuitry **180**, may increase effectiveness in addressing the type of detected condition (e.g., sleep apnea, snoring, tongue movement, etc.), and may be more comfortable for the patient.

In some embodiments, processor **144** may employ an iterative process in order to select modulation control signal parameters that result in a desired response level. For example, upon determining that a modulation control signal should be generated, processor **144** may cause generation of an initial modulation control signal based on a set of predetermined parameter values. If feedback from feedback circuit **148** indicates that a nerve has been modulated (e.g, if an increase in a degree of coupling is observed), then processor **144** may return to a monitoring mode by issuing sub-modulation control signals. If, on the other hand, the feedback suggests that the intended nerve modulation did not occur as a result of the intended modulation control signal or that modulation of the nerve occurred but only partially provided the desired result (e.g, movement of the tongue only partially away from the airway), processor **144** may change one or more parameter values associated with the modulation control signal (e.g., the amplitude, pulse duration, etc.).

Where no nerve modulation occurred, processor **144** may increase one or more parameters of the modulation control signal periodically until the feedback indicates that nerve modulation has occurred. Where nerve modulation occurred, but did not produce the desired result, processor **144** may re-evaluate the degree of coupling between primary antenna **150** and secondary antenna **152** and select new parameters for the modulation control signal targeted toward achieving a desired result. For example, where stimulation of a nerve causes the tongue to move only partially away from the patient's airway, additional stimulation may be desired. Because the tongue has moved away from the airway, however, implant unit **110** may be closer to external unit **120** and, therefore, the degree of coupling may have increased. As a result, to move the tongue a remaining distance to a desired location may require transfer to implant unit **110** of a smaller amount of power than what was supplied prior to the last stimulation-induced movement of the tongue. Thus, based on a newly determined degree of coupling, processor **144** can select new parameters for the stimulation control signal aimed at moving the tongue the remaining distance to the desired location.

In one mode of operation, processor **144** may be configured to sweep over a range of parameter values until nerve modulation is achieved. For example, in circumstances where an applied sub-modulation control signal results in feedback indicating that nerve modulation is appropriate, processor **144** may use the last applied sub-modulation control signal as a starting point for generation of the modulation control signal. The amplitude and/or pulse duration (or other parameters) associated with the signal applied to primary antenna **150** may be iteratively increased by predetermined amounts and at a predetermined rate until the feedback indicates that nerve modulation has occurred.

Processor **144** may be configured to determine or derive various physiologic data based on the determined degree of coupling between primary antenna **150** and secondary antenna **152**. For example, in some embodiments the degree of coupling may indicate a distance between external unit **120** and implant unit **110**, which processor **144** may use to determine a position of external unit **120** or a relative position of a patient's tongue. Monitoring the degree of coupling can also provide such physiologic data as whether a patient's tongue is moving or vibrating (e.g, whether the patient is snoring), by how much the tongue is moving or vibrating, the direction of motion of the tongue, the rate of motion of the tongue, etc.

In response to any of these determined physiologic data, processor **144** may regulate delivery of power to implant unit **110** based on the determined physiologic data. For example, processor **144** may select parameters for a particular modulation control signal or series of modulation control signals for addressing a specific condition relating to the determined physiologic data. If the physiologic data indicates that the tongue is vibrating, for example, processor **144** may determine that a sleep apnea event is likely to occur and may issue a response by delivering power to implant unit **110** in an amount selected to address the particular situation. If the tongue is in a position blocking the patient's airway (or partially blocking a patient's airway), but the physiologic data indicates that the tongue is moving away from the airway, processor **144** may opt to not deliver power and wait to determine if the tongue clears on its own. Alternatively, processor **144** may deliver a small amount of power to implant unit **110** (e.g., especially where a determined rate of movement indicates that the tongue is moving slowly away from the patient's airway) to encourage the tongue to continue moving away from the patient's airway or to speed its progression away from the airway. The scenarios described are exemplary only. Processor **144** may be configured with software and/or logic enabling it to address a variety of different

physiologic scenarios with particularity. In each case, processor **144** may be configured to use the physiologic data to determine an amount of power to be delivered to implant unit **110** in order to modulate nerves associated with the tongue with the appropriate amount of energy.

The disclosed embodiments may be used in conjunction with a method for regulating delivery of power to an implant unit. The method may include determining a degree of coupling between primary antenna **150** associated with external unit **120** and secondary antenna **152** associated with implant unit **110**, implanted in the body of a patient. Determining the degree of coupling may be accomplished by processor **144** located external to implant unit **110** and that may be associated with external unit **120**. Processor **144** may be configured to regulate delivery of power from the external unit **120** to the implant unit **110** based on the determined degree of coupling.

As previously discussed, the degree of coupling determination may enable the processor to further determine a location of the implant unit. The motion of the implant unit may correspond to motion of the body part where the implant unit may be attached. This may be considered physiologic data received by the processor. The processor may, accordingly, be configured to regulate delivery of power from the power source to the implant unit based on the physiologic data. In alternative embodiments, the degree of coupling determination may enable the processor to determine information pertaining to a condition of the implant unit. Such a condition may include location as well as information pertaining to an internal state of the implant unit. The processor may, according to the condition of the implant unit, be configured to regulate delivery of power from the power source to the implant unit based on the condition data.

In some embodiments, implant unit **110** may include a processor located on the implant. A processor located on implant unit **110** may perform all or some of the processes described with respect to the at least one processor associated with an external unit. For example, a processor associated with implant unit **110** may be configured to receive a control signal prompting the implant controller to turn on and cause a modulation signal to be applied to the implant electrodes for modulating a nerve. Such a processor may also be configured to monitor various sensors associated with the implant unit and to transmit this information back to external unit **120**. Power for the processor unit may be supplied by an onboard power source or received via transmissions from an external unit.

In other embodiments, implant unit **110** may be self-sufficient, including its own power source and a processor configured to operate the implant unit **110** with no external interaction. For example, with a suitable power source, the processor of implant unit **110** may be configured to monitor conditions in the body of a subject (via one or more sensors or other means), determining when those conditions warrant modulation of a nerve, and generate a signal to the electrodes to modulate a nerve. The power source could be regenerative based on movement or biological function; or the power sources could be periodically rechargeable from an external location, such as, for example, through induction.

Other embodiments of the present disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the present disclosure.

Additional aspects of the invention are described in the following numbered paragraphs, which are part of the description of exemplary embodiments of the invention. Each numbered paragraph stands on its own as a separate embodiment of the invention.

The invention claimed is:

1. A device for conveying power from a location external to a subject to a location within the subject, the device comprising:

a housing;

an electronics portion disposed within the housing, the electronics portion including at least one coil of electrically conductive material, the at least one coil configured to facilitate wireless power transfer to an implantable device, wherein the at least one coil includes a first coil of wire arranged on a first side of a dielectric carrier and a second coil of wire arranged on a second side of the dielectric carrier, the first coil of wire and the second coil of wire each having a plurality of windings; and

a mechanical connector associated with the housing configured to retain a flexible carrier and permit the housing to rotate relative to the flexible carrier, the flexible carrier including an adhesive and being configured for attachment to skin of the subject.

2. The device of claim **1**, wherein the mechanical connector is configured to permit more than about 360-degree rotation of the housing relative to the flexible carrier.

3. The device of claim **1**, wherein the mechanical connector is configured to permit rotation of less than about 360-degree rotation of the housing relative to the flexible carrier.

4. The device of claim **1**, wherein the at least one electrical connector includes a pair of electrical contacts arranged substantially equidistant from a center of the housing.

5. The device of claim **1**, wherein the at least one electrical connector includes a plurality of connectors in electrical communication with the electronics portion.

6. The device of claim **1**, further comprising at least one electrical connector associated with the housing in a manner permitting electrical connection to be maintained between the housing and the flexible carrier as the housing is rotated.

7. The device of claim **6**, wherein the electrical connector is configured to maintain a connection between the electronics portion and a battery associated with the flexible carrier.

8. A device for conveying power from a location external to a subject to a location within the subject, the device comprising:

a flexible carrier including a receiver, the flexible carrier being shaped to facilitate placement at the location external to the subject, the location external to the subject opposing the location within the subject;

at least one coil of electrically conductive material, wherein the at least one coil includes a first coil of wire arranged on a first side of a dielectric carrier and a second coil of wire arranged on a second side of the dielectric carrier, the first coil of wire and the second coil of wire each having a plurality of windings; and

a housing including a mechanical connector configured to mate with the receiver and permit the housing to rotate relative to the flexible carrier, wherein the at least one coil of electrically conductive material is located within the housing and configured to facilitate power transfer to an implant located at the location within the subject to modulate at least one nerve.

9. The device of claim **8**, wherein the flexible carrier further includes an electrical portion, the electrical portion configured to maintain electrical contact with at least one electrical connector associated with the housing as the housing is rotated.

10. The device of claim **9**, wherein the electrical portion includes conductive material arranged in a discontinuous circle.

11. The device of claim 10, wherein the electrical connector includes a pair of electrical contacts arranged substantially equidistant from a center of the housing.

12. The device of claim 11, wherein the distance of the electrical contacts from the center of the housing is substantially equal to a radius of the electrical portion.

13. The device of claim 9, wherein the electrical portion includes a pattern of discontinuous conductive material arranged on the flexible carrier.

14. The device of claim 9, wherein the flexible carrier further includes a battery.

15. A device for conveying power from a location external to a subject to a location within the subject, the device comprising:

a flexible carrier shaped to facilitate placement adjacent to the location within the subject,

an adhesive on a first side of the carrier;

at least one coil of electrically conductive material located within the housing and configured to facilitate power transfer to an implant located at the location within the subject to modulate at least one nerve, wherein the at least one coil includes a first coil of wire arranged on a first side of a dielectric carrier and a second coil of wire arranged on a second side of the dielectric carrier, the first coil of wire and the second coil of wire each having a plurality of windings; and

a mechanical connector associated with the carrier opposite the adhesive, wherein the mechanical connector is configured to retain a housing and permit the housing to rotate relative to the flexible carrier.

* * * * *